Petition

No. 81-1428

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1981

GRAND LABORATORIES, INC.,
Petitioner,

v.

RICHARD S. SCHWEIKER, SECRETARY
OF HEALTH AND HUMAN SERVICES,
Respondent.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

PETITION FOR CERTIORARI

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QUESTION PRESENTED

Whether the United States Food and Drug Administration, which is conceded to lack jurisdiction to regulate the manufacture and sale in interstate commerce of animal biological products (such jurisdiction being vested exclusively with the United States Department of Agriculture), nonetheless has jurisdiction pursuant to the Federal Food, Drug and Cosmetic Act to regulate those animal biologics which are manufactured and sold wholly within a single state.[1]

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[1]Richard S. Schweiker has succeeded Patricia Harris as Secretary of what is now the Department of Health and Human Services, and has thus been substituted as the defendant in this action. With that exception the caption of the case in this Court contains the names of all parties to the proceeding in the court whose judgment is sought to be reviewed. Grand Laboratories, Inc. is a closely held corporation and has no parent company or subsidiary or affiliated companies.

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
TABLE OF CONTENTS	ii
TABLE OF AUTHORITIES	iii
OPINIONS BELOW	1
STATEMENT OF JURISDICTION	2
STATUTES AND REGULATIONS INVOLVED	2
STATEMENT OF THE CASE	6
REASONS FOR GRANTING THE WRIT	12
CONCLUSION	17
APPENDIX	A-1

TABLE OF AUTHORITIES

Cases: **Page**

Animal Health Institute v. United States Department of Agriculture, 487 F.Supp. 376 (D. Colo. 1980) 9
Apex Hosiery Co. v. Leader, 310 U.S. 469, 513 (1940) 14
Boys Markets, Inc. v. Retail Clerks Union, Local 770, 398 U.S. 235, 250 (1970) 16
Cass v. United States, 417 U.S. 72, 78-79 (1973) 15
Croates v. Harrelson, 282 U.S. 55, 60 (1930) 15
Dawson Chemical Co. v. Rohm & Haas Co., 448 U.S. 176, 220-221, (1980) 16
Employees v. Missouri Public Health Dept., 411 U.S. 279, 286-287 (1973) 14
Flora v. United States, 357 U.S. 63, 64-65 (1957) 15
FTC v. Bunte Bros., Inc., 312 U.S. 349, 351, 354-355 (1941) 14
Heublein, Inc. v. South Carolina Tax Commission, 409 U.S. 275, 281-282 (1972) 14
Holy Trinity Church v. United States, 143 U.S. 457, 459 (1892) 15
Johnson v. Southern Pacific Co., 196 U.S. 1, 18 (1904) 15
Mastro Plastics Corp. v. NLRB, 350 U.S. 270, 285 (1955) 16
National Woodwork Mfrs. Assn. v. NLRB, 386 U.S. 612, 620 (1967) 15
New York State Department of Social Services v. Dublino, 413 U.S. 405, 413 (1973) 14
Philbrook v. Glodgett, 421 U.S. 707, 713 (1975) 15
Rewis v. United States, 401 U.S. 808, 812 (1971) 13
Richards v. United States, 369 U.S. 1, 11 (1962) 16

Scarborough v. United States, 431 U.S. 563, 572-577 (1977) 13
Schlanger v. Seamers, 401 U.S. 487, 490 fn.4 (1970) 15
Schwartz v. Texas, 344 U.S. 199, 202-203 (1952) 14
Stafford v. Briggs, 444 U.S. 527, 536 (1980) 15
Steelworkers v. Weber, 443 U.S. 193, 201-202 (1978) 15
Train v. Colorado Public Interest Research Group, Inc. 426 U.S. 1, 9-10 (1976) 15
TVA v. Hill, 437 U.S. 153, 187 n.33 (1978) 15
United States v. Amercian Trucking Assn., Inc., 310 U.S. 534, 542 (1940) 15
United States v. Bass, 404 U.S. 336, 349-350 (1971) 13
United States v. Culbert, 435 U.S. 371, 375 (1978) 15
United States v. Five Gambling Devices, 346 U.S. 441, 448-450 (1953) 13

Statutes:

Food and Drugs Act of 1906, Ch. 3915, 34 Stat. 768. 6

Food, Drug and Cosmetic Act, 21 U.S.C.
§301 et seq. ..... passim

21 U.S.C. 321(g)(1) ..... passim
21 U.S.C. §331(k) 11, 12
21 U.S.C. §392(a) 15
21 U.S.C. §392(b) ..... passim

Public Health Service Act of 1944, 42 U.S.C.
§262 et seq. 8, 10

Virus, Serum, Toxin Act of 1902,
Ch. 1378, 32 Stat. 728 ..... 6, 7, 8

Virus, Serum, Toxin Act of 1913,
21 U.S.C. §151-158. ..... passim

Regulations

21 CFR §7.1(f) 9
9 CFR §102.2(w) 7

Miscellaneous

Food and Drug Administration, *Legislative History of The Food, Drug and Cosmetic Act* (1980) 7, 8, 9

Report of The Secretary of Agriculture, 1910, 1911, 1912 7

Opinion 2424 (1940) Solicitor of The Department of Agriculture. 9

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ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
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PETITION FOR CERTIORARI

The Petitioner, Grand Laboratories, Inc., respectfully prays that a Writ of Certiorari be issued to review the judgment of the United States Court of Appeals for the Eighth Circuit entered in this proceeding on October 2, 1981.

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Eighth Circuit on rehearing en banc, reported at 660 F.2d 1288, appears in the Appendix at A-1. The opinion of the Court of Appeals, reported at 644 F.2d 729, appears in the Appendix at A-15. The opinion of the United States District Court for the District of South Dakota, reported at 488 F. Supp. 618, appears in the Appendix at A-29.

JURISDICTION

The United States Court of Appeals for the Eighth Circuit entered its judgment on March 25, 1981 and, after granting Respondent's petition for rehearing en banc, set aside such judgment and entered final judgment on October 2, 1981. On October 20, 1981 Petitioner filed a Motion for (further) rehearing en banc, which was denied on November 3, 1981. Petitioner invokes this Court's jurisdiction pursuant to 28 U.S.C. §1254(1).

STATUTES AND REGULATIONS INVOLVED

Statutes and Regulations Administered by the Food and Drug Administration.

> Section 6 of the Federal Food and Drugs Act of 1906:
>
> > That the term "drug," as used in this act, shall include all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals...

Section 201(g) of the Federal Food, Drug and Cosmetic Act [21 U.S.C. §321(g) (1)]:

> The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clauses (A), (B), or (C) of this paragraph; but does not include devices or their components, parts, or accessories.

Section 902(b) and (c) of the Federal Food, Drug and Cosmetic Act [21 U.S.C. §392(a) and (b)]:

> (a) Meat and meat food products shall be exempt from the provisions of this Act to the extent of the application or the extension thereto of the Meat Inspection Act, approved March 4, 1907, as amended (21 U.S.C. §601 et seq.)
>
> (b) Nothing contained in this chapter shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of section 262 of Title 42 (relating to viruses, serums, toxins, and analogous products applicable to man); the virus, serum, toxin, and analogous products provisions, applicable to domestic animals, of the Act of Congress approved March 4, 1913; ...

21 C.F.R. §7.1(f):

> "Product" means an article subject to the jurisdiction of the Food and Drug Administration, including any food, drug and device intended for human or animal use, any cosmetic and biologic intended for human use, and any item subject to a quarantine regulation under Part 1240 of this chapter ...

Section 301(k) of the Federal Food, Drug and Cosmetic Act [21 U.S.C. §331(k)]:

> The following acts and the causing thereof are hereby prohibited:
>
> * * *
>
> (k) The alteration, mutilation, destruction, obliteration, or removal of the whole or part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such articles being adulterated or misbranded.

The Virus, Serum Toxin Act of 1902 (recodified as the Public Health Service Act of 1944) [42 U.S.C. §262]:

> No person shall sell, barter, or exchange, or offer for sale, barter, or exchange in the District of Columbia, or send, carry, or bring for sale, barter, or exchange from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession, any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of diseases or injuries of man, unless (1) such virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product has been propagated or manufactured and prepared at an establishment holding an unsuspended and unrevoked license, issued by the Secretary as hereinafter authorized, to propagate or manufacture, and prepare such virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product for sale in the District of Columbia, or for sending, bringing, or carrying from place to place aforesaid; and (2) each package of such virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product is plainly marked with the proper name of the article contained therein, the name, address, and license number of the manufacturer, and the date beyond which the contents cannot be expected beyond reasonable doubt to yield their specific results. The suspension or revocation of any license shall not prevent the sale, barter, or exchange of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid

which has been sold and delivered by the licensee prior to such suspension or revocation, unless the owner or custodian of such virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid has been notified by the Secretary not to sell, barter, or exchange the same.

Section 351(g) of the Public Health Service Act of 1944 [42 U.S.C. §262(g)]:

> Nothing contained in this Act shall be construed as in any way affecting, modifying, repealing or superseding the provisions of the Federal Food, Drug, and Cosmetic Act (U.S.C., 1940 edition, title 21, ch. 9).

Statutes and Regulations Administered by the United States Department of Agriculture.

The Virus Serum Toxin Act of 1913 [21 U.S.C. §151]:

> It shall be unlawful for any person, firm, or corporation to prepare, sell, barter, or exchange in the District of Columbia, or in the Territories, or in any place under the jurisdiction of the United States, or to ship or deliver for shipment from one State or Territory or the District of Columbia to any other State or Territory or the District of Columbia, any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals, and no person, firm, or corporation shall prepare, sell, barter, exchange, or ship as aforesaid any virus, serum, toxin, or analogous product manufactured within the United States and intended for use in the treatment of domestic animals, unless and until the said virus, serum, toxin or analogous product shall have been prepared, under and in compliance with regulations prescribed by the Secretary of Agriculture, at an establishment holding an unsuspended and

unrevoked license issued by the Secretary of Agriculture as hereinafter authorized.

9 C.F.R. §101.2(w):

> Biological products. The term biological products, sometimes referred to as biologics, biologicals, or products, shall mean all viruses, serums, toxins, and analogous products of natural or synthetic origin, such as diagnostics, antitoxins, vaccines, live microorganisms, killed microorganisms and the antigenic or immunizing components of microorganisms intended for use in the diagnosis, treatment, or prevention of diseases of animals.

STATEMENT OF THE CASE

History of The Regulation Of Drugs And Biologics

This case presents an issue of statutory construction involving the interrelationship of the Federal statutes governing the manufacture and sale of drugs, human biologics and animal biologics. Human biologics were the first of such products to be subjected to Federal regulation, pursuant to the Virus, Serum, Toxin Act of 1902, Ch. 1378, 32 Stat. 728 (VST Act of 1902). Jurisdiction to regulate human biologics was at that time vested in the Public Health Service of the Department of the Treasury.

The first comprehensive Federal effort to regulate domestic commerce in drugs occurred four years later upon the enactment of the Federal Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768. The operative language of that Act defined "drug" as " ... any substance or mixture of substances intended to be used for the cure, mitigation or prevention of disease of either man or other animals ..." Jurisdiction over drugs at that time was vested in the Bureau of Chemistry of the Department of Agriculture.

In 1910, the Secretary of Agriculture sought authority to supervise the importation and preparation for sale in

interstate commerce of animal biologics, such authority to be "similar to that already vested in the Public Health Service with regard to such products used in human medicine". Report of the Secretary of Agriculture to the President, 1910, at 15. In 1911 and 1912 the Secretary in his Reports emphasized the need for legislation granting him authority to regulate animal biologics. 1911 Report at 24, 1912 Report at 28. In 1913, Congress established Federal regulation over animal biologics pursuant to the Virus, Serum, Toxin Act of 1913, which is presently codified at 21 U.S.C. §151-158 (VST Act of 1913). Pursuant to that Act the term "biologic" is currently defined at 9 C.F.R. §101.2(w), as:

> [A]ll viruses, serums, toxins and analogous products ... intended for use in the diagnosis, treatment, or prevention of diseases of animals.

The Federal Food and Drugs Act of 1906 was revised extensively in 1938 with the enactment of the Federal Food, Drug and Cosmetic Act, now codified at 21 U.S.C. 301 et seq. (FD&C Act). The definition of the term "drug" in the 1906 Act was amended in the FD&C Act to delete the words "any substance or mixture of substances" and to substitute the term "articles", leaving the definition which is at issue in this case as follows:

> The term "drug" means ...
> (B) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals ...

During the legislative debates on the FD&C Act concern was raised as to how that Act would affect other legislation, in particular the VST Act of 1902 governing *human* biologics. 79 Cong. Rec. 5018 (1935), 4 Leg. Hist. 56.[1] Despite assurances by the sponsor of the FD&C Act that the measure contained no authority over biological products, the Director of the Public Health Service proposed an amendment to the FD&C Act which would prevent what he nonetheless regarded as a

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[1]The Food and Drug Administration published in 1980 a comprehensive legislative history of the FD&C Act, which is cited herein as ____ Leg. Hist. ____.

potential for conflict of authority and the possibility of duplication of work. 4 Leg. Hist. 209-210. This amendment with minor revisions, was enacted as §902(c) of the FD&C Act, 21 U.S.C. §392(b), which provided as follows:

> Nothing contained in this Act shall be construed as in any way affecting, modifying, repealing or superseding the provisions of the Virus, Serum, Toxin Act of July 1, 1902...
>
> 6 Leg. Hist. 474

No reference was made in the legislative history of the FD&C Act to *animal* biological products.

In 1939, the Public Health Service was transferred from the Department of the Treasury to the newly-created Federal Security Agency (FSA). In 1940, the Food and Drug Administration (FDA), which was then a part of the Department of Agriculture, was also transferred to FSA, thereby placing regulation of *human* biologics and drugs within the same agency. In 1944, as a part of an overall consolidation of laws relating to the Public Health Service, the VST Act of 1902 was recodified in the Public Health Service Act (PHS Act of 1944), 42 U.S.C. §262 *et seq.* Subsequent reorganizations resulted in the transfer of authority to administer the PHS Act of 1944 from the Public Health Service to what is now the Bureau of Biologics of FDA, where it remains as of this time.

In the mid-1960's the practice of adding antibiotics to animal feed had become widespread and FDA's procedures for clearing animal drugs came to be regarded as overly complicated, leading to long regulatory delays. See 23 Leg. Hist. 625, 24 Leg. Hist. 654-655.As a result, proposals to streamline such procedures were ultimately enacted as the Animal Drug Amendments of 1968. In commenting on this legislation the Secretary of Agriculture noted that the term "new animal drug" in the proposed Animal Drug Amendments "could be interpreted" so as to bring animal biologics within its scope. 23 Leg. Hist. 642-643. He further noted that this would result in a duplication of work and

would "serve no useful purpose." 23 Leg. Hist. 643. The Secretary of Agriculture thus proposed an amendment to the Animal Drug Amendments, so that §902(c) of the FD&C Act, which already made it clear that human biologics did not come within that Act, would also provide that animal biologics were exempt as well. The Secretary's proposed amendment was enacted as §107 of the Animal Drug Amendments of 1968. 82 Stat. 353. The section-by-section analysis of the bill in the House Report thereon describes that provision [then §106] as follows:

> This section makes a technical amendment making clear that the Act does not supersede the virus, serum, toxin and analogous products provisions of the Act of March 4, 1913 ...
>
> 24 Leg. Hist. 430, *see also* 24 Leg. Hist. 659.

Since the enactment of the VST Act of 1913 the Department of Agriculture has construed that Act as encompassing only animal biologics shipped in interstate commerce. This interpretation was affirmed in *Animal Health Institute v. USDA*, 487 F. Supp. 376 (D. Colo. 1980). In addition, an interpretation of §902(c) by the Solicitor of USDA, which was issued shortly after the effective date of the FD&C Act, stated that the statutes enumerated in §902(c) should be regarded as being "paramount and exclusive in the means of control over the articles falling within their respective scopes". The Solicitor also pointed out that, in contrast, the exemption set forth in Section 902(b) of the FD&C Act, 21 U.S.C. 392(a), (which exempts meat products only to the extent covered by other Federal regulation),was "not a complete one, but [exempts] only to the extent necessary to allow full application and effect of the Meat Inspection Act". Solicitor's Opinion No. 2424, (USDA) dated May 6, 1940. Further, FDA published a regulation in 1978 setting forth the scope of its jurisdiction, which made specific reference to human biologics but made no reference to animal biologics. See 21 CFR §7.1(f).

In early 1979, the division of regulatory jursidiction over drugs and biologics may thus be summarized as follows:

regulation of both human and animal drugs was vested in FDA pursuant to the FD&C Act; human biologics were also regulated by FDA pursuant to the PHS Act of 1944; animal biologics shipped in interstate commerce were subject to the jursdiction of USDA pursuant to the VST Act of 1913; and animal biologics produced for sale within a single state were regulated exclusively by the States.

Procedural History Of This Litigation.

Animal biologics are products prepared from animal tissues or fluids, or from microorganisms, used for the prevention or treatment of diseases in animals. Petitioner, Grand Laboratories, Inc., is located in Freeman, South Dakota. The firm is owned and operated by Dr. Duane Pankratz, a practicing veterinarian. A portion of Grand Laboratories' products are "autogenous" bacterins, that is, products prepared from bacterial cultures taken from selected animals in a herd for use by veterinarians in treating infections within that specific herd only. The products of Grand Laboratories are distributed wholly within the State of South Dakota and the firm is subject to regulation by the South Dakota Department of Agriculture pursuant to S.D. Code §39-18-1 to 39-18-53 (1980).

On July 17, 1979, FDA commenced a "pilot program" to assert jurisdiction over animal biological laboratories operating on an intrastate basis. When an attempt was made to exercise jurisdiction over Grand Laboratories, that firm brought this action seeking a declaratory judgment[2] that FDA has no jurisdiction over animal biologics, and further seeking an injunction barring the agency from inspecting or otherwise attempting to exercise its jurisdiction over the Petitioner. FDA argued before the District Court that animal biologics come within the broad definition of "drugs" in the FD&C Act, 21 U.S.C. 321(g) (1) (B), thus granting to FDA jurisdiction over all such products. FDA further argued that §902(c) of the FD&C Act, 21 U.S.C. 392(b), as amended by the Animal Drug Amendments of 1968, should be read as an

[2]Jurisdiction in the District Court was based upon 28 U.S.C. §1331.

"exemption" provision, but which exludes only those animal biologics which travel in interstate commerce from its otherwise comprehensive jurisdiction. FDA argued in this regard that since intrastate animal biologics are not subject to the VST Act of 1913 in the first place, FDA jurisdiction over such products would not "affect" or "modify" that Act, and would hence be consistent with §902(c).[3] FDA further argued that the agency has commerce clause jurisdiction over the intrastate production and sale of animal biologics by Grand Laboratories pursuant to §301(k) of the FD&C Act, 21 U.S.C. 331(k), on the basis that an alleged "active" (nonbiological) component of one of Grand Laboratories' products allegedly travelled in interstate commerce.[4]

After a hearing before the District Court, Chief Judge Fred J. Nichol determined that Congress did not intend that animal biologics be included within the FD&C Act's definition of "drug", and that the 1968 Amendment to §902(c) confirmed the status quo. The District Court therefore granted the preliminary injunction sought by Grand Laboratories. The Government appealed, and a panel of the Eighth Circuit Court of Appeals, in an opinion issued by Senior Circuit Judge Gibson, affirmed the District Court's judgment, Judge Arnold dissenting. The Government then successfully moved for rehearing en banc, and upon rehearing the Court of Appeals, in an opinion issued by Judge Arnold, reversed the District Court, Judges Heaney and Bright dissenting, and remanded the case with instructions to dismiss Grand Laboratories' complaint.

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[3]Petitioner contended that the legislative history and administrative interpretations of the Act demonstrated that animal biologics were not intended to come within the definition of the term drug in the first place, and that §902(c) merely confirmed that such was the case.

[4]Inasmuch as the District Court determined that FDA had no jurisdiction over animal biologics, it never reached the issue as to whether §301(k) would provide commerce clause jurisdiction over intrastate biologics solely on the basis that a non-biological component had travelled in interstate commerce, nor did the District Court make any findings in this regard.

REASONS FOR GRANTING THE WRIT

1. The Eighth Circuit Court of Appeals Has Decided An Important Question Involving Federal/State Relations That Has Not Been, But Should Be, Settled By This Court.

The preparation of animal biological products in local laboratories for use by State-licensed veterinarians, for sale within the State of manufacture, is essentially an adjunct to the practice of veterinary medicine, and as such has traditionally been subject to regulation by the States pursuant to the police power. For over sixty-five years the U.S. Department of Agriculture has regulated the manufacture of animal biologics for sale in interstate commerce, and State Departments of Agriculture or State Veterinarians have regulated the production and sale of such products on an intrastate basis. The decision of the Eighth Circuit Court of Appeals threatens to disrupt seriously this long standing Federal/State balance of regulatory responsibilty, and will surely create considerable confusion[5] as to the boundaries of the jurisdiction of FDA and the States.

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[5]FDA argued to the District Court that it had commerce clause jurisdiction pursuant to §301(k) of the FD&C Act 21 U.S.C. 331(k)), only if an active ingredient of an intrastate manufacturer's product travelled in interstate commerce. Since FDA has issued no regulations nor any Standards of Identity and Purity for animal biologics, it is impossible for such manufacturers to know what ingredients FDA considers to be "active", and thus can only guess as to which if any of its products are considered by FDA to be subject to its jurisdiction. Furthermore, to rest the question of jurisdiction on whether a particular product contains an interstate ingredient is totally unworkable. Manufacturers of intrastate animal biological products in the more industrialized states that have the ability to purchase all of their ingredients from in-state sources may continue to be regulated by their state regulatory agency, whereas laboratories operating in more rural areas, such as Grand Laboratories in South Dakota, will be faced with the prospect of either bearing the high costs and regulatory delays of unneeded federal regulation, or discontinuing the production of those products that require interstate ingredients, to the detriment of veterinarians and farmers who rely on such products.

It is clear that the majority of the Eighth Circuit Court of Appeals based its decision primarily on the belief that comprehensive Federal regulation is in the public interest. The majority seems to further believe that a presumption should be made that Federal regulation exists, and that it is up to Congress to spell out those areas that are reserved to the States. This case thus raises a fundamental issue of Federal/State relations: in the absence of clear language granting a Federal agency regulatory jurisdiction over an area of commerce that has traditionally been regulated exclusively by the States, should the Federal Courts assume the existence of comprehensive Federal jurisdiction and as a matter of course resolve ambiguities in Federal statutes in favor of such regulation; or in the alternative, should the Federal judiciary refuse to extend Federal commerce power in such instances, and instead to insist that when Congress wishes to extend the commerce power to regulate an aspect of intrastate commerce that it so do in clear and explicit language.

This Court has stated on a number of occasions that when Congress desires to extend Federal authority in matters affecting the States, it should make such intention clear. For example, in the construction of the language of Federal criminal statutes, this Court has established the principle that in cases involving conduct readily denounced as criminal by the States, Congress will not be deemed to have significantly changed the Federal/State balance unless Congress has conveyed its purpose clearly. *United States v. Bass*, 404 U.S. 336, 349-350 (1971). See also *United States v. Five Gambling Devices*, 346 U.S. 441, 448-450 (1953) (plurality opinion). This Court has also noted that the absence of clear legislative history demonstrating an intent to expand Federal authority is of significance in determining whether such authority actually exists. *See Scarborough v. United States*, 431 U.S. 563, 572-577 (1977); *Rewis v. United States*, 401 U.S. 808, 812 (1971). In cases involving questions of Federal supremacy, this Court has also established the principle that it will not be presumed that a Federal Statute was intended to supersede the exercise of the power of a State unless there is a clear manifestation by

Congress of an intention to do so. *Schwartz v. Texas*, 344 U.S. 199, 202-203 (1951); *Employees v. Missouri Public Health Dept.*, 411 U.S. 279, 286-287 (1973); *Heublein, Inc. v. South Carolina Tax Commission*, 409 U.S. 275, 281-282 (1972); *New York State Department of Social Services v. Dublino*, 413 U.S. 405, 413 (1973). A similar requirement for a clear manifestation of intent to extend the commerce power has also been expressed by this Court. *See Apex Hosiery Co. v. Leader*, 310 U.S. 469, 513 (1940); *FTC v. Bunte Bros., Inc.*, 312 U.S. 349, 351, 354-355 (1941).

Grand Laboratories submits that to require a clear manifestation of Congressional intent to extend Federal regulation over areas of commerce traditionally regulated by the States would be more consistent with our Federalist system of government than the approach used in this case by the Eighth Circuit Court of Appeals.

2. By Ignoring The Applicable Legislative History The Eighth Circuit Decided This Case In A Way That Conflicts With Applicable Decisions Of This Court.

Upon a review of the legislative history of the Federal statutes dealing with drugs and biologics, it is readily apparent that Congress never intended that animal biologics be subject to regulation by FDA pursuant to the Federal Food, Drug and Cosmetic Act (FD&C Act). Further, FDA's own long standing administrative interpretation of the statutes in question flatly contradicts that agency's present claim of jurisdiction. The *only* way in which the majority of the Court of Appeals could construe the FD&C Act in a manner that would uphold FDA's claim of jurisdiction was to ignore the interrelationship of the several statutes involved and the relevant legislative histories and prior administrative interpretations in question. The majority relied solely on the allegedly "plain language" of the definitions section of the FD&C Act 201(g) (1) (B), 21 U.S.C 321(g) (1) (B), while at the same time giving an uncommonly restrictive meaning to the words of what FDA contends is an exemption provision in that same Act, §902(c), 21 U.S.C. §392(b). The majority of the Court of Appeals justified ignoring the legislative history and

administrative interpretations of the statutes in question by quoting (at A-8) the aphorism of Mr. Justice Holmes that *"[w]e do not inquire what the legislature meant,* we ask only what the statute means." (emphasis added). In fact, such an approach to statutory construction is directly contrary to the rule long established by this Court that Federal courts must construe Federal statutes so as to give effect to the intent of Congress. *Stafford v. Briggs,* 444 U.S. 527, 536 (1979); *Train v. Colorado Public Interest Research Group, Inc.,* 426 U.S. 1, 9-10 (1976); *Philbrook v. Glodgett,* 421 U.S. 707, 713 (1975); *National Woodwork Mfrs. Assn. v. NLRB,* 386 U.S. 612, 620 (1967); *United States v. American Trucking Assn.* 310 U.S. 534, 542 (1940); *Johnson v. Southern Pacific Co.,* 196 U.S. 1, 18 (1904); and *Holy Trinity Church v. United States,* 143 U.S. 457, 459 (1892). *See also Steelworkers v. Weber,* 443 U.S. 193, 201-202 (1978); *United States v. Culbert,* 435 U.S. 371, 375 (1978); *Cass v. United States,* 417 U.S. 72, 78-79 (1973); *Schlanger v. Seamers,* 401 U.S. 487, 490 fn. 4 (1970); and *Flora v. United States,* 357 U.S. 63, 64-65 (1957).

The Court of Appeals misread this Court's opinion in *TVA v. Hill,* 437 U.S. 153, 187 n.33 (1978) (quoting *Croates v. Harrelson,* 282 U.S. 55, 60 (1930)). Indeed, this Court went to great care to demonstrate that its reading of the statute which was the subject of the *TVA* decision was fully consistent with the intent of Congress as demonstrated by the applicable legislative history, 437 U.S. at 168, 174-185. In this case, although the expansive definition of "drug" can be read to include animal biologics, the definitions section of the FD&C Act must nonetheless be interpreted in light of what FDA contends is the "exemption" provision of that Act,§902(c). If a plain meaning approach is used in construing this "exemption" language as well, it is clear that FDA is entirely excluded from regulation of *all* animal biologics. *Compare* §902(c) with §902(b) [21 U.S.C. 392(a)]. It is through a twisted and illogical interpretation of §902(c) that the Court of Appeals reached the conclusion that statutory authority exists for FDA to regulate intrastate biologics, despite the fact that it is concededly barred from regulating the interstate sale of these same products.

Statutory interpretation requires more than concentration upon isolated words; rather, consideration must be given to the total corpus of pertinent law and the policies that inspired ostensibly inconsistent provisions. *Boys Markets, Inc. v. Retail Clerks Union, Local 770*, 398 U.S. 235, 250 (1970). It is fundamental that a section of a statute should not be read in isolation from the context of the whole Act. *Richards v. United States*, 369 U.S. 1, 11 (1962); see also *Mastro Plastics Corp. v. NLRB*, 350 U.S. 270, 285 (1955). It is apparent that the majority of the Court of Appeals had a policy preference in favor of comprehensive Federal regulation, and ignored the relevant legislative history, the long-standing administrative interpretations of the relevant statutory provisions and the plain language of §902(c) in order to achieve the desired results. As this Court recently noted in *Dawson Chemical Co. v. Rohm & Haas Co.*, 448 U.S. 176, 220-221, (1980), in the task of statutory construction, questions of public policy cannot be determinative of the outcome unless specific policy choices can be fairly attributed to Congress itself. In this case Congress in recent years has given consideration[6] to expanding Federal jurisdiction over intrastate animal biologics, but has not yet acted in that regard. The courts should not go beyond the statutory scheme Congress has enacted. For over sixty-five years the regulation of intrastate animal biologics has been vested exclusively in the States. If FDA believes public policy considerations require comprehensive Federal regulation over this area of commerce, it is for Congress, not the judiciary, to grant such authority.

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[6]H.R. 14318 (95th Congress), the Animal Biologics Act of 1978, was introduced by Representative Wampler on October 12, 1978. H.R. 4853, (96th Congress), which was similar proposed legislation, was introduced on July 18, 1979. No action was taken on either of these bills.

CONCLUSION

For these reason, a Writ of Certiorari should issue to review the judgment of the Eighth Circuit Court of Appeals.

Respectfully submitted,

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Appendix

APPENDICES

APPENDIX A

IN THE

United States Court of Appeals

FOR THE EIGHTH CIRCUIT

No. 80-1331

GRAND LABORATORIES, INC.,
Appellee,

v.

PATRICIA HARRIS, SECRETARY OF HEALTH, EDUCATION, and WELFARE,
Appellant.

On Appeal from the United States District Court for the District of South Dakota

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Sumitted: June 15, 1981

Filed: October 2, 1981

Before LAY, Chief Judge, HEANEY, BRIGHT, ROSS, STEPHENSON, HENLEY, McMILLIAN, and ARNOLD, Circuit Judges, *en banc.*

ARNOLD, Circuit Judge.

This is a suit by Grand Laboratories, Inc., to enjoin the Food and Drug Administration from inspecting its facilities in South Dakota. Grand manufactures animal biologics, which are products prepared from animal tissues or fluids, or from microorganisms, and used for the prevention or treatment of disease in animals. Plaintiff distributes its product wholly within the state of South Dakota, but some ingredients are shipped interstate to Grand's laboratory. The FDA argued that it had the right to inspect Grand's facilities because animal biologics are "drugs" within the meaning of the Food,

Drug, and Cosmetic Act, 21 U.S.C. §321(g) (1) (B), which defines "drug" to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals . . . ." The District Court relying on later Acts of Congress which will be detailed below, disagreed with FDA and held that animal biologics are not "drugs" for present purposes. It therefore issued the injunction prayed for. *Grand Labs., Inc.* v. *Harris,* 448 F. Supp. 618 (D.S.D. 1980). A panel of this Court affirmed, one judge dissenting. *Grand Labs., Inc.,* v. *Harris,* 644 F.2d 729 (8th Cir. 1981). We then granted the FDA's petition for rehearing en banc, and now, after hearing argument, we reverse the District Court.

I.

An understanding of the issue presented in this case requires a brief summary of statutory law in the field of drugs and biologics. A number of relevant propositions are undisputed. Laboratories making animal biologics for sale interstate are subject to regulation by the Department of Agriculture, and have been since the enactment of the Virus, Serum and Toxin Act of 1913 (VSTA), 21 U.S.C. §§151-58. That Act provides in part:

> It shall be unlawful for any person, firm, or corporation to prepare, sell, barter, or exchange in any place under the jurisdiction of the United States, or to ship or deliver for shipment from one State or Territory or the District of Columbia, any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals; and no person, firm, or corporation shall prepare, sell, barter, exchange, or ship as aforesaid any virus, serum, toxin, or analogous product manufactured within the United States and intended for use in the treatment of domestic animals, unless and until the said virus, serum, toxin, or analogous product shall have been prepared, under and in compliance with regulations prescribed by the Secretary of

> Agriculture, at an establishment holding an unsuspended and unrevoked license issued by the Secretary of Agriculture as hereinafter authorized.

21 U.S.C. §151.

It is agreed, on the other hand, that the VSTA does not authorize the Agriculture Department to regulate animal biologics manufactured and distributed wholly within one state, as Grand's products are, even if a component used in the biologic has passed through interstate commerce. See *Animal Health Inst. v. USDA*, 487 F. Supp. 376 (D. Colo. 1980).

It is also clear that all animal biologics, whether interstate or intrastate, are within the literal definition of "drug" in FDA's governing statute, the Food, Drug, and Cosmetic Act of 1938. That definition, in full, is as follows:

> (g) (1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clauses (A), (B), or (C) of this paragraph; but does not include devices or their components, parts, or accessories.

21 U.S.C. §321(g) (1). The portion of this definition that is relevant for present purposes originated in the Food and Drug Act of 1906, 34 Stat. 768, 769, which defined "drug" to include "any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals."

In an attempt to harmonize these provisions, both sides point to Section 902(c) of the Food, Drug, and Cosmetic Act (FDCA), as amended in 1968, 21 U.S.C. §392(b). This statute provides:

> (b) Nothing contained in this chapter shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of section 262 of Title 42 (relating to viruses, serums, toxins, and analogous products applicable to man); the virus, serum, toxin, and analogous products provisions, applicable to domestic animals, of the Act of Congress approved March 4, 1913; the Filled Cheese Act of June 6, 1896, the Filled Milk Act of March 4, 1923; or the Import Milk Act of February 15, 1927.

Thus, we know that the FDCA does not modify or affect the power of the Department of Agriculture under the VSTA of 1913 over interstate animal biologics. Grand contends, and the District Court held, that Section 902(c) also bars FDA from regulating intrastate animal biologics. (It is agreed that the FDCA, read without reference to the harmonizing clause contained in Section 902(c), would validly give FDA power to regulate animal biologics sold intrastate, if an ingredient of the products had previously been transported interstate.) Under Grand's view, it is subject to no federal regulation. FDA, on the other hand, would read Section 902(c) more literally. If a product is not subject to the VSTA (as intrastate animal biologics are not), it must, according to FDA, remain subject to its jurisdiction under the FDCA, assuming the product is within the words of the FDCA's definition of "drug" (as intrastate animal biologics concededly are). FDA's view, if accepted, would subject both interstate and intrastate animal biologics to federal regulation, although, perhaps anomalously, the regulation would be by different agencies.

II.

This case concerns products admittedly used for the prevention or treatment of disease in animals. The particular product around which the dispute here centers is known as "porcine mastitis-metritis-arthritis-infertility bacterin." This bacterin contains, among other ingredients, aluminum hydroxide (itself a "drug"), which, according to evidence

introduced in the court below, was purchased by the plaintiff Grand Laboratories, Inc., from a chemical firm in New Jersey and then shipped to South Dakota for use in the manufacturing process.

There is thus no doubt that the product involved here is within the literal definition of "drug" that Congress has adopted. Grand urges us not to apply the words of the statute as written for two main reasons: (1) the interpretation thus produced is unreasonable; and (2) Congress, by its actions in later years, primarily in 1913 and 1968, has shown that it really did not mean what it said in 1906.

We start with the proposition, recently repeated by the Supreme Court, that

> When we find the terms of the statute unambiguous, judicial inquiry is complete, except "in 'rare and exceptional circumstances.' " *TVA v. Hill*, 437 U.S. 153, 187, n. 33 (1978) (quoting *Crooks v. Harrelson*, 282 U.S. 55, 50 (1930)).

Rubin v. United States, 49 U.S.L. Week 4103, 4104 (U.S. January 21, 1981).[1] That Court has affirmed this principle with special force in respect of the very definition at issue in this case. In *United States v. An Article of Drug ... Bacto-Unidisk* ... 394 U.S. 784 (1969), the question was whether a laboratory aid known as an antibiotic sensitivity disc, used in a screening test for help in determining the proper antibiotic drug to administer to patients, was a "drug" within the meaning of 21 U.S.C. §321(g)(1)(B), notwithstanding the fact that it was used exclusively in laboratory work and never came in contact with any part of the patient's body. The Supreme Court reversed holdings by two courts below that the antibiotic discs were not drugs. The Court said:

> . . . Congress fully intended that the Act's coverage be as broad as its literal language indicates . . ..

394 U.S. at 798. The Court also referred, *ibid.*, to "the well-

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[1]See also *United States Railroad Retirement Bd. v. Fritz*, 49 U.S.L. Week 4035, 4039 (U.S. December 9, 1980): "the language of the statute is clear, and we have historically assumed that Congress intended what it enacted."

accepted principle that remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health . . . ."

The significance of this holding for present purposes is enhanced when it is recalled that the effect of a contrary holding in *Bacto-Unidisk* would probably not have been to exempt the discs from regulation altogether, since, if they had not been held to be "drugs," they would almost certainly have been considered "devices," and thus subject to regulation, though to a lesser extent, under another provision of the statute. Here, by contrast, a holding that animal biologics are not "drugs" would leave those substances, in cases where they are not actually shipped in their finished form across state lines, entirely free of all federal regulation.

The District Court ably argued that the result advocated by the Food and Drug Administration here would be illogical, in that certain kinds of animal biologics, those shipped across state lines, would be regulated by the Department of Agriculture, whereas certain other kinds, those not shipped across state lines but composed in part of ingredients that had been so shipped, would be regulated by the Food and Drug Administration. The resulting regulatory scheme, to be sure, is not so symmetrical as it could be, and if one were casting a vote in Congress, the arguments for placing the regulation of all animal biologics in the Department of Agriculture, as opposed to the Food and Drug Administration, would be strong indeed. It seems to us, however, that judges should usually resist the temptation to superimpose their own ideas of reason and logic on the clear words of a congressional enactment. We do not believe that a literal construction of this statute yields "results so manifestly unreasonable that they could not be attributed to congressional design . . .." *United States v. Rutherford*, 442 U.S. 544, 555 (1979). It is no more reasonable, in our view, to conclude that Congress, despite the concededly unambiguous words of the 1906 statute, did not intend in that enactment to regulate animal biologics at all.

It is true that this construction of the statute leaves some questions unanswered about the subsequent conduct of the Congress. If, for example, animal biologics had already been regulated by the Act of 1906, why did Congress, in the Virus, Serum, Toxin Act of 1913 subject those products, when shipped interstate, to regulation by the Department of Agriculture? The question is a fair one, and we do not know the answer for certain. We do suggest, however, that when Congress enacts two provisions with respect to a given subject that appear to be inconsistent or conflicting, it is our duty to harmonize the provisions and to give effect to both of them to the extent possible. Here, the 1913 Act can be given full effect as written, without superseding the jursidiction previously conferred over products of the kind at issue in this case by the 1906 Act. Grand rightly directs our attention to the Animal Drug Amendments of 1968, §107 of which, 82 Stat. 342, is now codified at 21 U.S.C. §392(b). This provision makes clear that the Food, Drug, and Cosmetic Act does not affect, modify, repeal, or supersede the Virus, Serum, Toxin Act of 1913. Plaintiff reads these words as indicating a general intention on the part of Congress not to regulate animal biologics at all except as expressly provided in the 1913 Act. The words need not be so read. Their literal meaning is simply to leave the regulation of animal biologics shipped across state lines in the Department of Agriculture, where it had been since 1913. No reference is made to the Act of 1906, and no such reference should be implied, in view of the universally received doctrine that repeals by implication are not favored.

It is perfectly true that Congress can act to cure the anomaly of FDA regulation of intrastate animal biologics, if it is an anomaly. It is equally true that Congress could overrule a holding by the courts that the Food and Drug Administration has the power to regulate animal biologics sold intrastate. The real question is, who shall bear the risk that, for reasons of inertia or otherwise, Congress may not act at all? We think it better that the risk be borne by the private parties seeking to avoid all federal regulation, rather than by the public agency seeking to defend the public health. No doubt there are cases when the literal meaning of a statute is absurd, and we

are not, in those instances, obliged to abandon our common sense. In most cases, however, the safer course is to apply the law as written, secure in the knowledge that if we do so we cannot justly be accused of usurpation, and that a power exists that can correct us. In short, this is a case in which we should apply the aphorism of Mr. Justice Holmes that "[w]e do not inquire what the legislature meant; we ask only what the statute means." Holmes, *The Theory of Legal Interpretation.* 12 Harv. L. Rev. 417, 419 (1899).

III.

The judgment of the District Court is reversed, and this cause is remanded to it with instructions to dismiss Grand's complaint.

HEANEY, Circuit Judge with whom BRIGHT, Circuit Judge, joins, dissenting.

Human biologics have been regulated since 1902 by a succession of agencies leading to what is now the Food and Drug Administration (FDA), and animal biologics have been regulated since 1913 by the Department of Agriculture (USDA).[1] Throughout this period, animal biologics manufactured and distributed exclusively within a state ("intrastate" products)[2] have been exempt from all federal regulation because they were exempted by Congress from the USDA's jurisdiction. *See Animal Health Inst. v. USDA,* 487 F. Supp. 376 (D. Colo. 1980). The FDA for the first time now claims jurisdiction over such intrastate products, asserting latent statutory authority which has laid

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[1]The district court decision by Judge Nichol sets forth an excellent summary of the complex administrative history of this regulatory subject. See 488 F. Supp. 618, 621-626 (D. S.D. 1980).

[2]One ingredient of the animal biologics at issue in this case appears to be shipped in interstate commerce, which is necessary to the FDA's asserted jurisdiction. The biologics are nonetheless deemed "intrastate" to reflect the basis for their exemption from USDA jurisdiction. *See A-1, A-3.*

dormant for more than seventy years. Although we share the majority's belief that all animal biologics should be subject to federal regulation, we cannot find authority for the FDA to claim jurisdiction over those that only flow in intrastate commerce. The jurisdiction principle transcends any consideration of our personal preferences — the FDA cannot invoke regulatory jurisdiction that Congress has exclusively conferred upon another agency. Moreover, the practical result of the majority's decision appears so unreasonble that no Congress could have intended it — one agency with nearly seventy years of experience regulating animal biologics will continue to regulate such products in interstate commerce, while a separate agency will now develop and duplicate the same expertise in order to regulate the same products as they move in intrastate commerce. Our shared desire to see the intrastate animal biologics regulated by the federal government cannot outweigh the plain intent of Congress nor the common sense of sound public administration. We therefore dissent.

I.

As the majority emphasizes, animal biologics come within the definition of "drug" in the Food, Drug and Cosmetic Act (FDCA) and, therefore nominally come within the FDA's jurisdiction, A-3. It is clear that the facial scope of the FDCA reaches animal biologics in both interstate and intrastate commerce. *Id.* A literal application of the FDCA, however, must account for section 902(c) of the Act, now codified, as amended, at 21 U.S.C. §392(b), which the majority acknowledges but which bears repeating here:

> (b) Nothing contained in this chapter shall be construed as *in any way affecting, modifying, repealing, or superseding* the provisions of section 262 of Title 42 (relating to viruses, serums, toxins, and analogous products applicable to man); the virus, serum, toxin, and analogous products

> provisions, applicable to domestic animals, of *the Act of Congress approved March 4, 1913;* the Filled Cheese Act of June 6, 1896; the Filled Milk Act of March 4, 1923; or the Import Milk Act of February 15, 1927. [Emphasis added.]

The 1913 Act that the FDCA shall not "affect or modify" is the Virus-Serum-Toxin Act of 1913 (VSTA), which confers upon the USDA jurisdiction over animal biologics. Both the district court and the Circuit Court panel read this "shall not affect" language as affirming the status quo—which since 1913 has meant animal biologics are regulated exclusively by the USDA.[3] The FDA contends, and the majority now agrees, that the VSTA will not be "affected or modified" if the FDA regulates intrastate animal biologics because such products have always been exempt from the USDA's jurisdiction under the Act. A-4, A-7. When Congress provides that the VSTA shall govern animal biologics and that the FDCA "shall not affect" the VSTA, it seems plain to us that the FDCA cannot be authority to regulate what the VSTA exempts. Indeed, the "shall not affect" language is a restriction on FDA jurisdiction, not a grant of authority. Even more persuasive is the fact that the FDA's contention is contrary to the legislative history on this question, to the FDA's prior longstanding interpretation of its jurisdiction and to the only case law construing the intent of Congress with respect to animal biologics.

The FDA's claim of authority arises from the jurisdictional definition of "drug" in the Pure Food and Drug Act of 1906. A-4. Although animal biologics were in use at the time the 1906 Act was adopted, the FDA can point to nothing in the legislative history of that Act which address regulation of such products. Moreover, if Congress intended the 1906 Act to encompass such products, there would have been no need to pass a separate, independent animal biologics act just seven years later — the VSTA of 1913 which confers jurisdiction upon the USDA for such regulation. *Cf.*,

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[3]See *Grand Labs., Inc. v. Harris*, 488 F. Supp. 618 (D. S.D. 1980); *Grand Labs., Inc. v. Harris*, 644 F.2d 729 (8th Cir. 1981) (Judge Arnold dissenting).

Teamsters v. Daniel, 439 U.S. 551, 569-570 (1979). A simple amendment to the 1906 Act, or even no legislative clarification at all, might be consistent with the FDA's assertion of jurisdiction, but passage of a wholly independent act providing separate treatment of such products flatly contradicts the agency's contention. The majority considers this legislative history a source of "unanswered questions." A-7, but it actually provides one clear answer: Congress intended animal biologics to be regulated exclusively pursuant to the 1913 VSTA and not the 1906 Act on which the FDA now relies.

The longstanding jurisdictional interpretation by the FDA also clashes with its current claim. Since 1938, the FDA has acknowledged in regulations that animal biologics subject to VSTA "shall not be deemed subject" to the drug provisions of the FDCA. 3 Fed. Reg. 1847 § 1.02 (1938); 21 Fed. Reg. 5577 §130.2 (1956). Even the FDA's regulations dealing with enforcement actions do not explicitly include animal biologics within their scope. For example, 21 C.F.R. §7.1(f) (1980) defines products to include "an article subject to the jurisdiction of the Food and Drug Administration, including any food, drug, and device intended for human or animal use, any cosmetic and *biologic intended for human use*, ****." (Emphasis added.) If the FDA considered all biologics, both animal and human, to be within its jurisdiction, there would have been no need to modify the term biologic by the phrase "intended for human use." Not until 1979 did the FDA, through litigation, attempt to assert any jurisdictional authority over animal biologics.

In addition, the only reported case construing the legislative intent of VSTA flatly contradicts the FDA's contention. In *Animal Health Inst. v. USDA*, 487 F. Supp. 376 (D. Colo. 1980), the court rejected the claim of a private party that sought to compel the USDA to regulate intrastate animal biologics. The majority cites this case as authority that the USDA cannot regulate such intrastate products, A-3, but ignores the essential rationale on which that decision relied. The court in *Animal Health* ruled that Congress

specifically intended to exempt intrastate animal biologics from regulation, noting a long line of USDA administrative decisions in accord with that intent.[4] To permit the FDA to now assert the same jurisdiction wholly negates the intent of Congress. Moreover, such congressional intent underlying the VSTA exemption removes any reasonable doubt concerning section 902(c) of the FDCA — by declaring in section 902(c) that the FDCA shall not "affect or modify" the VSTA, Congress could hardly have intended a change removing VSTA's exemption for intrastate products.

To conclude that Congress intended for exclusive USDA jurisdiction seems inescapable from the foregoing legislative history, administrative practice and judicial precedent.

II.

Perhaps most compelling are the practical results of permitting FDA jurisdiction in this case, results which appear to be "so manifestly unreasonable that they could not be attributed to congressional design ****." *United States v. Rutherford*, 442 U.S. 544, 555 (1979). Indeed, the majority concedes that the results may be "illogical," "not symmetrical," and "anomalous" A-6, A-7. The consequence of the majority's decision is that the FDA will have exclusive jurisdiction over animal biologics manufactured and distributed within a state's borders and the USDA will have exclusive jurisdiction over the very same products when they cross a state's borders. Thus, two agencies must develop duplicative expertise, train personnel for identical functions, and route inspectors along the same geographic paths — all to regulate products that are only distinguishable by their point of destination. It is difficult to imagine that Congress intended this result when it conferred

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[4]Although the court found the legislative history of VSTA to be "extremely sparse," it ruled that such history was "supportive of the view that Congress did not intend to require licensing of manufacturers who confine their activities to one state." *Animal Health Inst. v. USDA*, 487 F. Supp. 376, 378 (D. Colo. 1980). After noting that the USDA has, since 1913, interpreted the VSTA as exempting intrastate animal biologics, the court indicated that such an interpretation "is consistent with the literal meaning of [the Act and] follows the intent of Congress." *Id.*, at 379.

jurisdiction over the interstate products upon the USDA and exempted the intrastate products from regulation.

In the face of legislative history, prior FDA determinations, judicial precedent and administrative common sense all weighing in favor of exclusive USDA jurisdiction, the majority turns to the "broad remedial purpose" of the FDCA to find authority for FDA jurisdiction, relying on *United States v. An Article of Drug.....Bacto-Unidisk.....*,A-5, A-6. We agree that the FDCA has such a broad purpose and that Act should be liberally construed to further that purpose. *Bacto-Unidisk* and the policy it espouses, however, simply do not apply to the present case. As the majority notes, the product involved in *Bacto-Unidisk* would either be deemed a "drug" or a "device" within the definition of the FDCA. A-6. Although the degree fo FDA regulation would be more stringent if the product was deemed a "drug," the FDA would clearly have jurisdiction regardless of the definition the product fell under. Here, the question is whether the FDA has any jurisdiction in light of the express grant of authority to the USDA over animal biologics and the express restriction on the FDCA's scope. We cannot accept the conclusion that the general purpose behind a statute provides so sweeping a souce of authority that it could outweigh an express restriction imposed within the same statute.

The majority properly notes that Congress has the power to overrule this Court, but then indicates that the risk of congressional inertia should fall on those that would resist federal regulation. A-7, A-8. This sentiment seems misplaced in the present context. It is axiomatic that a regulatory agency has the authority and only such authority as may be conferred upon it by Congress. Where, as here, Congress has granted exclusive jurisdiction to another agency and has chosen to exempt altogether some element of that jurisdiction, there is no "risk of inertia" for courts to

allocate — there simply is no authority to regulate the exempted subject matter.

It should be noted that denying the FDA's claim of jurisdiction would not render intrastate biologics free of all regulation, as the majority implies. A-7. The State of South Dakota has a comprehensive statutory framework that defines the permissible bounds for manufacturing, labeling and distributing a broad range of animal remedies. See S.D. Code §§ 39-18-1 to 39-18-53 (1980)[5]

The Congress thus is free to confer intrastate jurisdiction upon the USDA, or even upon the FDA, or to leave such matters in the hands of state authorities as it has since 1913. In any case, because Congress has spoken once, it is for that institution, not the courts, to formulate any new regulatory arrangement.

A true copy.

Attest:

CLERK, U.S. COURT OF APPEALS, EIGHTH CIRCUIT

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[5]The record before us, however, does not reveal the extent of enforcement activity at the state level.

APPENDIX B

United States Court of Appeals

FOR THE EIGHTH CIRCUIT

No. 80-1331

Grand Laboratories, Inc., *Appellee,*	*	
v.	*	Appeal from the United States District Court for the District of South Dakota
Patricia Harris, Secretary of Health, Education and Welfare, *Appellant.*	*	

Submitted: January 14, 1981
Filed: March 25, 1981

Before HEANEY, Circuit Judge, GIBSON, Senior Circuit Judge, and ARNOLD, Circuit Judge

GIBSON, Senior Circuit Judge

This case presents the question whether animal biologics constitute drugs within the meaning of the Federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 321(g)(1) (1976).

I.

In February 1979, two field officers from the Food and Drug Administration (FDA) attempted to inspect the facilities of Grand Laboratories, Inc. (Grand) in Freeman, South Dakota. They were denied entrance. In August 1979, the FDA obtained a warrant from a United States magistrate to inspect Grand's facility. Before the warrant was enforced, Grand brought suit in the United States District Court for the District of South Dakota seeking declaratory and injunctive relief

against the FDA on the grounds that the FDA is without jurisdiction to regulate the manufacture and sale of animal biologics. After issuing a temporary restraining order, the District Court held a hearing on whether a preliminary injunction should issue against the FDA. On February 21, 1980, the District Court filed a memorandum opinion and issued a preliminary injunction. *Grand Laboratories, Inc. v. Harris*, 488 F. Supp. 618 (D. S.D. 1980). The Secretary of Health, Education and Welfare filed a timely appeal.

Grand manufactures and distributes animal biologics wholly within the state of South Dakota. Animal biologics are products prepared from animal tissues or fluids or growth of microorganisms, used for the prevention or treatment of disease in animals.

Grand successfully argued in the District Court[1] that Congress granted sole federal regulatory power over the manufacture and sale of animal biologics to the United States Department of Agriculture (USDA) under the Virus, Serum, Toxin Act of 1913, 21 U.S.C. §§ 151-158 (1976). That act provides in part:

> It shall be unlawful for any person, firm, or corporation to prepare, sell, barter, or exchange in any place under the jurisdiction of the United States, or to ship or deliver for shipment from one State or Territory or the District of Columbia, any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals, and no person, firm, or corporation shall prepare, sell, barter, exchange or ship as aforesaid any virus, serum, toxin, or analogous product manufactured within the United States and intended for use in the treatment of domestic animals, unless and until the said virus, serum, toxin, or analogous product shall have been prepared, under and in compliance with regulations prescribed by the Secretary of Agriculture, at an establishment holding an

[1]The Honorable Fred J. Nichol, Senior Judge, United States District Court, District of South Dakota.

> unsuspended and unrevoked license issued by the Secretary of Agriculture as hereinafter authorized.

21 U.S.C. § 151.

Under the Virus, Serum, Toxin Act of 1913, the USDA has limited commerce clause jurisdiction. The agency does not have jurisdiction over animal biologics manufactured and distributed wholly within one state, even though a component used in the biologic may have passed through interstate commerce. *See Animal Health Institute v. USDA*, 487 F. Supp. 376 (D. Colo. 1980).

The FDA contended in the District Court that animal biologics were drugs within the meaning of the FDCA. The FDCA defines the term "drug" as follows:

> (g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clauses (A), (B), or (C) of this paragraph; but does not include devices or their components, parts, or accessories.

21 U.S.C. § 321(g)(1) (1976).

The FDA argued in the District Court that because animal biologics were drugs within the meaning of the FDCA the agency retained jurisdiction over their intrastate manufacture. The FDA conceded that 21 U.S.C. § 392(b) (1976) deprived it of jurisdiction over the interstate manufacture and distribution of animal biologics.[2] See A-20,

[2]Section 392(b) provides in part: "nothing contained in this chapter shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of *** the virus, serum, toxin and analogous products provisions, applicable to domestic animals, of the Act of Congress approved March 4, 1913."

A-21. The District Court, however, disagreed with the FDA's premise that animal biologics were drugs within the meaning of the FDCA. The court based this finding on the statutory history of both the FDCA and the Virus, Serum, Toxin Act of 1913:

> The FDA has correctly pointed out that great weight should be given to an agency's construction of a statute. The definition of "drug," however, appears to have already been construed as not encompassing animal biologics. As mentioned above, the USDA procured the passage of the VSTA in 1913. At that time the Food and Drug Act of 1906 was administered by the USDA and the definition of "drug" contained in that act was apparently not viewed as encompassing animal biologics. The basic definition of "drug" was not materially changed in the meantime. And the circumstances surrounding the inclusion of the VSTA in section 392(b) indicates that Congress concurred with the USDA interpretation.

Grand Laboratories, Inc., 488 F. Supp. at 622.

On appeal, the FDA contends the District Court erred in finding it to be without jurisdiction over the intrastate manufacture and distribution of animal biologics. We find animal biologics not to be drugs within the meaning of the FDCA and affirm the District Court.

II.

"The starting point in every case involving construction of a statute is the language itself." *Teamsters v. Daniel*, 439 U.S. 551, 558 (1979). In spite of the use of animal biologics at the time of the original enactment of the predecessor to the FDCA, the Pure Food Act of 1906, animal biologics were mentioned in neither the statute nor the legislative history of the FDCA, nor in the Pure Food Act of 1906. Despite this lack of any support, in the form of congressional intent, for the inclusion of animal biologics, the FDA maintains that animal biologics are "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals," and therefore come within the literal definition of section 321(g)(1)(B) of title 21.

Neither we nor Grand nor the FDA disagree that a literal reading of the above section includes animal biologics. The "essential question for our determination is whether Congress intended the definition of drug [as set forth in the FDCA] to have the broad coverage" that the literal language would allow. *United States v. Bacto-Unidisk*, 394 U.S. 784, 793 (1969). Reviewing the legislative history of the FDCA and the Virus, Serum, Toxin Act of 1913 and the lack of prior enforcement activity by the FDA, we find that Congress did not intend to include animal biologics within the meaning of the definition of the term "drug" in the FDCA. In so finding, we recognize the remedial nature of the FDCA and give due deference to the FDA's interpretation of the act. *Id.*, 394 U.S. at 798; *see Teamsters v. Daniel*, 439 U.S. at 566 n.20; *National Nutritional Foods Association v. Mathews*, 557 F.2d 325, 336 (2d Cir. 1977).

III.

In reviewing the legislative history of the pertinent acts, we are mindful of the Supreme Court's warning that "[o]nly when a literal construction of a statute yields results so manifestly unreasonable that they could not fairly be attributed to congressional design will an exception to statutory language by judicially implied." *United States v. Rutherford*, 442 U.S. 544, 555 (1979). In order to fully understand the complex interplay of the FDCA and the Virus, Serum, Toxin Act of 1913, it is necessary to review congressional action in the human as well as the animal biologics area, in relation to congressional regulation of traditional drugs.

Federal regulation of human biologics began in 1902 when Congress enacted a statute prohibiting the importation or interstate shipment of any virus, serum, toxin, antitoxin, or analogous products unless licensed by the Treasury Department and properly labelled. Act of July 1, 1902, ch. 1378, 32 Stat. 728. Four years later, Congress enacted the Pure Food Act of 1906, ch. 3915, 34 Stat. 768. The act contained a broad definition of the term "drug" which was continued in the FDC Act of 1938. Neither the statutory history of the

human biologics act of 1902 nor of the Pure Food Act of 1906 contain any cross-references to each other. The Pure Food Act appears to have been enacted with the intention of being independent of any of the provisions of the human biologics act enacted in 1902.

In 1913, Congress passed the Virus, Serum, Toxin Act of 1913. The FDA admits that the legislative history contains no discussion of the Virus, Serum, Toxin Act's relationship to the Pure Food Act of 1906. In 1938, Congress strengthened the FDA's power to protect the public from dangerous drugs by enacting the FDC Act. Once again neither the statute itself nor its history contains any reference to animal biologics.[3] Section 902(c) of the FDCA, however, did provide that the act did not affect, modify, or supersede the 1902 act regulating human biologics, but this section was later subject to the congressional revision of the human biologics act in 1944. *See* A-21. No reference was made at that time to animal biologics, but section 902(c) was later amended, in 1968, to include the Virus, Serum, Toxin Act of 1913 relating to animal biologics. The amendment exempted the 1913 (animal biologics) act from the jurisdiction and coverage of the FDCA.

Section 902(c) is now codified, as amended, at 21 U.S.C. §392(b) (1976), which provides:

> (b) Nothing contained in this chapter shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of section 262 of Title 42 (relating to viruses, serums, toxins, and analogous products applicable to man); the virus, serum, toxin, and analogous products provisions, applicable to domestic animals, of the Act of Congress approved March 4, 1913; the Filled

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[3]Originally, responsibility for enforcement of the Pure Food and Drug Act of 1906, the Virus, Serum, Toxin Act of 1913, and the FDCA of 1938 were placed in divisions of the Department of Agriculture. These were, respectively, the Bureau of Chemistry, the Bureau of Animal Husbandry, and the Food and Drug Administration. Subsequently, the FDA became part of the Department of Health, Education and Welfare, now Health and Human Services. *See Grand Laboratories, Inc.*, 488 F. Supp. at 620-21.

Cheese Act of June 6, 1896; the Filled Milk Act of March 4, 1923; or the Import Milk Act of February 15, 1927.

The first explicit congressional connection between the Virus, Serum, Toxin Act of 1913 and the FDCA occurred with the passage of the Animal Drug Amendments of 1968, Pub. L. No. 90-399, § 107, 82 Stat. 342 (codified at 21 U.S.C. § 392(b) (1976)). This amendment expanded the "not affecting, modifying, repealing or superseding" language to include the Virus, Serum, Toxin Act of 1913.

Our review of the statutory history of the meaning of the term "drug"in the FDCA and its forerunner, the Pure Food Act of 1906, reveals that for a period of over 55 years, Congress never considered animal biologics to be drugs under the FDA's jurisdiction. In fact, when the relationship between human biologics and the FDCA was first explicitly considered in 1944, Congress reacted by making clear that human biologics were to be subject to the FDCA. In the Virus, Serum, and Toxin Act of 1944, ch. 373, Title III, § 351, 58 Stat. 702, relating to human biologics, Congress intended that the FDCA also apply to human biologics.[4] "Subsection (g) [of § 351, codified at 42 U.S.C. § 262(g) (1976)] is an explicit statement, confirming the present legal situation, that products subject to this section are not exempted from the Federal Food, Drug, and Cosmetic Act, ***."[5] H.R. Rep. No. 1364, 78th Cong., 2d Sess. _____, *reprinted in* [1944] U.S.

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[4]Jurisdiction to enforce the human biologics acts originally was placed in the Public Health Service, which in 1902 was a division of the Treasury Department. In 1939 the Public Health Service was transferred from Treasury to the newly created Federal Security Agency which was transferred to Health, Education and Welfare, now Health and Human Services. In 1940, the FDA and its functions were transferred to the Federal Security Agency. Therefore, as contrasted with animal biologics, see note 3, *supra*, human biologics, both as a drug under the FDCA and as human biologics under the 1944 act, have been administered by the same department since the date of the enactment of the 1944 act. *See Grand Laboratories, Inc.*, 488 F. Supp. at 620-21.

[5]42 U.S.C. § 262(g) provides: "nothing contained in this chapter shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act."

CODE CONG. & AD. NEWS 1211, 1234; see *United States v. Calise*, 217 F. Supp. 705, 708-09 (S.D.N.Y. 1962) (human blood both a drug and a human biologic).

Later, in 1968, when Congress considered the relationship between the FDCA and animal biologics, the reaction was markedly different. The FDA admits that section 107 of the Animal Drug Amendments of 1968, codified at 21 U.S.C. §392(b) added the Virus, Serum, Toxin Act of 1913 "to the exempting provisions of section 902(c) of the FDC Act, 21 U.S.C. § 392(b)." Appellant's brief at 20. As stated by the District Court, the "intended effect of section 392(b) [1968 amendment] is maintenance of the status quo." *Grand Laboratories, Inc.*, 488 F. Supp. at 622. We agree. Animal biologics are not to be considered drugs within the meaning of the FDCA.

IV.

The FDA also argues that we should defer to its interpretation of the meaning of the term "drug" in the FDCA, the statute which the FDA is responsible for administering. "But there are limits, grounded in the language, purpose, and history of the particular statute, on how far an agency may go in its interpretative role." *Teamsters v. Daniel*, 439 U.S. at 566. Since 1938, the FDA has acknowledged in regulations that animal biologics subject to the Virus, Serum, Toxin Act of 1913 "shall not be deemed subject" to the drug provisions of the FDCA. 3 Fed. Reg. 1847 § 1.02 (1938); 21 Fed. Reg. 5577 § 130.2 (1956). Even the FDA's regulations dealing with enforcement actions do not explicitly include animal biologics within their scope. 21 C.F.R. § 7.1(f) (1980) defines products to include "an article subject to the jurisdiction of the Food and Drug Administration, including any food, drug, and device intended for human or animal use, any cosmetic and biologic intended for human use, *** ." If the FDA considered all biologics, both animal and human, to be within its jurisdiction, there would have been no need to modify the term biologic by the phrase "intended for human use." Not until 1979 did the FDA, through litigation, attempt to exert any jurisdictional authority over animal biologics.

The FDA argues that excluding animal biologics from inclusion in the FDCA would result in a "loophole" in the regulation of intrastate animal biologics. Congress, in passing the Virus, Serum, Toxin Act of 1913, did not fully exercise its power under the commerce clause, as construed in later Supreme Court decisions. *See, e.g., Heart of Atlanta Motel, Inc. v. United States*, 379 U.S. 241, 258-59 (1964); *NLRB v. Jones & Laughlin Steel Corp.*, 301 U.S. 1, 36-41 (1937). Animal biologics manufactured and distributed wholly in one state remain free from the strictures of federal regulation. The legislative issue over whether a modern-day "loophole" exists is unrelated to the judicial question of whether animal biologics were included in the meaning of the term "drug" in the Pure Food Act of 1906 and later the FDCA.

In short, Congress has created any so-called "loophole" in the federal regulation of intrastate animal biologics. It is therefore for Congress,[6] and not the Judicial branch, to remedy the situation if it sees fit to do so.

V.

The existence of the Virus, Serum, Toxin Act of 1913, coupled with the FDA's lack of enforcement activity during the past century, severely undercut all arguments for extending the FDCA to animal biologics. The statutory history leaves little doubt but that Congress believed it was filling a regulatory void when it enacted the Virus, Serum, Toxin Act of 1913. If Congress believed animal biologics were included within the term "drug" in the Pure Food and Drug Act of 1906, there would have been no need for a separate animal biologics act. Even if additional regulatory powers were perceived to be needed in the area of animal biologics, Congress could have remedied the matter by amending the 1906 act. Instead, Congress enacted a separate, independent statute to regulate animal biologics. *Cf. Teamsters v. Daniel*, 439 U.S. at 569-70. Animal biologics were not thought to be

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[6]In the last session of Congress, a bill was introduced to expand the jurisdiction of the United States Department of Agriculture to the intrastate manufacture and distribution of animal biologics. H.R. 4853, 96th Cong. (1978).

regulated under the Pure Food Act of 1906 and the FDC Act of 1938 at the time of their enactment. Animal biologics have been accorded separate and different treatment under the Virus, Serum, Toxin Act of 1913 from the treatment accorded more traditional medications under the FDCA. Animal biologics at this time do not constitute drugs within the meaning of the FDCA. If federal jurisdiction is deemed advisable, Congress can fill this alleged void at any time it seems fit.

Affirmed.

ARNOLD, Circuit Judge, dissenting.

The Food and Drug Act of 1906, 34 Stat. 768, 769, defines "drug," in pertinent part, as "any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals." This definition has been carried forward into present law without significant change. Section 201(g) of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, 21 U.S.C. §321(g), now reads as follows:

> (g)(1) The term "drug" means . . . (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals....

This case concerns animal biologics, admittedly used for the prevention or treatment of disease in animals. The particular product around which the dispute here centers is known as "porcine mastitis-metritis-arthritis-infertility bacterin." This bacterin contains, among other ingredients, aluminum hydroxide, which, according to evidence introduced in the court below, was purchased by the plaintiff Grand Laboratories, Inc., from a chemical firm in New Jersey and then shipped to South Dakota for use in the manufacturing process.

There is thus no doubt, and the Court raises none, that the product involved here is within the literal definition of "drug" that Congress has adopted. As I read its opinion, the Court declines to apply the words of the statute as written for two main reasons: (1) the interpretation thus produced is

unreasonable; and (2) Congress, by its actions in later years, primarily in 1913 and 1968, has showed that it really did not mean what it said in 1906. Because I cannot agree that the literal language of the statute should not be applied in the circumstances of this case, I respectfully dissent.

I start with the proposition, recently repeated by the Supreme Court, that

> When we find the terms of the statute unambiguous, judicial inquiry is complete, except "in 'rare and exceptional circumstances.' " *TVA v. Hill*, 437 U.S. 153, 187, n. 33 (1978) (quoting *Crooks v. Harrelson*, 282 U.S. 55, 60 (1930)).

Rubin v. United States, 49 U.S.L. Week 4103, 4104 (U.S. January 21, 1981).[1] That Court has affirmed this principle with special force in respect of the very definition at issue in this case. In *United States v. An Article of Drug ... Bacto-Unidisk* ...., 394 U.S. 784 (1969), the question was whether a laboratory aid known as an antibiotic sensitivity disc, used in a screening test for help in determining the proper antibiotic drug to administer to patients, was a "drug" within the meaning of 21 U.S.C. § 321(g)(1)(B), notwithstanding the fact that it was used exclusively in laboratory work and never came in contact with any part of the patient's body. The Supreme Court reversed holdings by two courts below that the antibiotic discs were not drugs. The Court said:

> ...Congress fully intended that the Act's coverage be as broad as its literal language indicates ....

394 U.S. at 798. The Court also referred, *ibid.*, to "the well-accepted principle that remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health ...."

The significance of this holding for present purposes is enhanced when it is recalled that the effect of a contrary holding in *Bacto-Unidisk* would probably not have been to

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[1]See also *United States Railroad Retirement Bd. v. Fritz*, 49 U.S.L. Week 4035, 4039 (U.S. December 9, 1980): "the language of the statute is clear, and we have historically assumed that Congress intended what it enacted."

exempt the discs from regulation altogether, since, if they had not been held to be "drugs," they would almost certainly have been considered "devices," and thus subject to regulation, though to a lesser extent, under another provision of the statute. Here, by contrast, the Court's holding that animal biologics are not "drugs" leaves those substances, in cases where they are not actually shipped in their finished form across state lines, entirely free of all federal regulation.

The Court persuasively argues that the result advocated by the Food and Drug Administration here would be illogical, in that certain kinds of animal biologics, those shipped across state lines, would be regulated by the Department of Agriculture, whereas certain other kinds, those not shipped across state lines but composed in part of ingredients that had been so shipped, would be regulated by the Food and Drug Administration. The resulting regulatory scheme, to be sure, is not so symmetrical as it could be, and if one were casting a vote in Congress, the arguments for placing the regulation of all animal biologics in the Department of Agriculture, as opposed to the Food and Drug Administration, would be strong indeed. It seems to me, however, that judges should usually resist the temptation to superimpose their own ideas of reason and logic on the clear words of a congressional enactment. I cannot bring myself to believe that a literal construction of this statute would yield "results so manifestly unreasonable that they could not be attributed to congressional design ...." *United States v. Rutherford*, 442 U.S. 544, 555 (1979). It is no more reasonable, in my view, to conclude that Congress, despite the concededly unambiguous words of the 1906 statute, did not intend in that enactment to regulate animal biologics at all.

It is true that the construction of the statute I am arguing for leaves some questions unanswered about the subsequent conduct of the Congress. If, for example, animal biologics had already been regulated by the Act of 1906, why did Congress, in the Virus, Serum, Toxin Act of 1913, now codified as 21 U.S.C. §§151-58, subject those products, when shipped interstate, to regulation by the Department of Agriculture? The question is a fair one, and I do not know the answer. I do suggest, however, that when Congress enacts

two provisions with respect to a given subject that appear to be inconsistent or conflicting, it is our duty to harmonize the provisions and to give effect to both of them to the extent possible. Here, the 1913 Act can be given full effect as written, without superseding the jurisdiction previously conferred over products of the kind at issue in this case by the 1906 Act. The Court rightly directs our attention to the Animal Drug Amendments of 1968, § 107 of which, 82 Stat. 342, is now codified at 21 U.S.C. §392(b). This provision makes clear that the Food, Drug, and Cosmetic Act does not affect, modify, repeal, or supersede the Virus, Serum, Toxin Act of 1913. The Court reads these words as indicating a general intention on the part of Congress not to regulate animal biologics at all except as expressly provided in the 1913 Act. The words need not be so read. The literal meaning is simply to leave the regulation of animal biologics shipped across state lines in the Department of Agriculture, where it had been since 1913. No reference is made to the Act of 1906, and no such reference should be implied, in view of the universally received doctrine that repeals by implication are not favored.

It is perfectly true, as the Court observes, *ante*, A-24, that Congress can act to fill the void created by this case, if it is a void. It is equally true that Congress could overrule a holding by the courts that the Food and Drug Administration has the power to regulate animal biologics sold intrastate. The real question is, who shall bear the risk that, for reasons for inertia or otherwise, Congress may not act at all? I would prefer that risk be borne by the private parties seeking to avoid all federal regulation, rather than by the public agency seeking to defend the public health. No doubt there are cases when the literal meaning of a statute is absurd, and we are not, in those instances, obliged to abandon our common sense. In most cases, however, the safer course is to apply the law as written, secure in the knoweldge that if we do so we cannot justly be accused of usurpation, and that a power exists that can correct us. In short, I believe this is a case in which we should apply the aphorism of Mr. Justice Holmes that "we do not inquire what the legislature meant; we ask only what the statute means." Holmes, Collected Legal Papers 207 (1920).

I would reverse the judgment below.[2]

A true copy.

Attest:

CLERK, U.S. COURT OF APPEALS EIGHTH CIRCUIT.

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[2]The Court argues, *ante*, A-22, that "[s]ince 1938, the FDA has acknowledged in regulations that animal biologics subject to the Virus, Serum, Toxin Act of 1913 'shall not be deemed subject' to the drug provisions of the FDCA." As I understand the cited regulation, however, it did not disclaim altogether any FDA jurisdiction over animal biologics, but simply provided that "a new drug shall not be deemed subject to ... the [FDC] Act, if it is subject to the [VSTA] ...." 3 Fed. Reg. 1847, §1.02 (1938). It is undisputed that the animal biologics at issue here are not subject to the VSTA. The clear implication of the Department of Agriculture's 1938 regulation, therefore, is that these biologics are subject to the FDCA.

APPENDIX C

UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH DAKOTA
SOUTHERN DIVISION

CIV79-4126

Grand Laboratories, Inc.,

Plaintiff,

vs.

Patricia Harris, Secretary of
Health, Education and Welfare,

Defendant.

MEMORANDUM DECISION

Qualley, Larson & Jones, of Sioux Falls, South Dakota, appeared in behalf of the plaintiff;

Mr. John J. Ulrich, Assistant United States Attorney, of Sioux Falls, South Dakota, and Mr. Frederick H. Degnan, Assistant Chief Counsel, Food and Drug Administration, Department of Health, Education and Welfare, Rockville, Maryland, appeared in behalf of the defendant.

This case, involving the interplay between the Virus, Serum, and Toxin Act of 1913 (VSTA), 21 U.S.C. section 151 et seq., and the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. section 301 et seq., is one of first impression. Plaintiff is a South Dakota corporation engaged in the production and marketing of animal biologics. Defendant is joined in her capacity as supervisor of the Food and Drug Administration (FDA). Defendant obtained a search warrant from the United States Magistrate directed against the plaintiff's facility. Plaintiff brought this action seeking declaratory and injunctive relief against the FDA on the grounds that the FDA has not been empowered by Congress to regulate the manufacture and sale of animal biologics. A temporary restraining order was issued and a hearing on a motion for preliminary injunction set. The FDA elected to move for dismissal rather than file an answer.

The parties basically agree on the facts relevant to the issue of jurisdiction. The plaintiff apparently manufactures and sells animal biologics wholly within the state of South Dakota. Animal biologics are products prepared from animal tissues or fluids or growth of microorganisms used for the prevention or treatment of disease in animals. The particular product around which this dispute has centered is known as "Porcine Mastitis-Metritis-Arthritis-Infertility Bacterin" (Bacterin). The antigen (the biological component intended to produce an immune response) in the Bacterin is an organism known as Streptococcus equisimilus. The Bacterin also contains an adjuvant, a substance that is intended to enhance the immune response to the antigen. The particular adjuvant used in the Bacterin is aluminum hydroxide. The FDA introduced evidence tending to show that aluminum hydroxide is not produced in South Dakota and, further, that plaintiff had purchased aluminum hydroxide from a chemical firm in New Jersey.

The gravamen of the plaintiff's contention is that the VSTA granted sole federal regulatory power over the manufacture and sale of animal biologicals to the United States Department of Agriculture (USDA). The grant of jurisdiction to the USDA only reaches animal biologicals delivered or offered for delivery in interstate commerce; regulation of animal biologics produced and marketed on an intrastate basis, even where a component has passed through interstate commerce, being left to the various states.[1] In support of its contention that the federal regulation of animal biologics rests solely with the USDA the plaintiff points to the following language in the FDCA:

> Nothing contained in this Act shall be construed as in any way affecting, modifying, repealing, or superseding...the virus, serum, toxin, and analogous products provisions, applicable to

[1]The USDA has apparently recognized that the VSTA does not grant jurisdiction over "intrastate" animal biologics that merely have a component that has passed through interstate commerce. An attorney for the USDA so represented in proceedings in another District. Animal Health Institute v. USDA, Civ. No. 78-K-796 (D. Colo. 1979).

> domestic animals, of the Act of Congress approved March 4, 1913....

21 U.S.C. section 392(c) (1970). The obvious implication of the plaintiff's position is that no federal agency has congressional authority to regulate plaintiff's activities.

The FDA contends that the Bacterin is a drug within the meaning of the FDCA and that jurisdiction exists because a component, the adjuvant aluminum hydroxide, has passed through interstate commerce. The FDA views the language of 21 U.S.C. 392(c) as precluding it from asserting jurisdiction only over animal biologicals subject to regulation by the USDA. As the VSTA does not grant the USDA jurisdiction over animal biologicals produced and distributed within the boundaries of a single state, the FDA contends that it has jurisdiction over such "intrastate" biologicals when one of the components has passed through interstate commerce.

Both parties have pointed to legislative history, prior enactments, and the past practices of various agencies in support of their interpretation of 21 U.S.C. section 392(c). Our inquiry must, of course, start with the language of the provision. "Though we may not end with the words in construing a disputed statute, one certainly begins there." F. Frankfurter, Some Reflections on the Reading of Statutes, 16 (1943); quoted with approval in Andrus v. Allard, ____ U.S. ____, ____ (1979) (48 U.S.L.W. 4013, 4014). By the combination of words used in section 392(c), Congress seems to have said that what the VSTA hath wrought let not the FDCA lay assunder. The histories of the various acts dealing with the purity and effectiveness of food and drugs, and biologicals for animals and humans indicate that the VSTA was intended as the sole federal effort in the regulation of animal biologics.

Adulterated or unwholesome drugs, along with food and liquor, were first subjected to federal regulation in 1890. See, Ch. 839 section 2, 26 Stat. 415. This first effort only applied to articles imported into the United States or its territories. In 1902 an Act was passed regulating the interstate commerce of human biologics. Act of July 1, 1902, ch. 1378, 32 Stat. 728. The 1902 Act was administered by the Public Health Service, at that time a division of the Treasury Department.

The Food and Drug Act of 1906 provided for the regulation of food, drugs, and liquor placed in interstate commerce. Act of June 30, 1906, ch. 3915, 34 Stat. 768. The Act applied to articles received or delivered in "original unbroken packages" having passed through interstate commerce. *Id.*, section 2, 34 Stat. at 768. The term "drug" was defined as including "all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or animals." *Id.*, section 6, 34 Stat. at 769. Although this definition has received some subsequent embellishment, it remains substantially the same. Primary responsibility for enforcement of the Act was assigned to the Bureau of Chemistry in the Department of Agriculture. See, Appropriations Act for Dept. of Agriculture, March 4, 1917, ch. 179, 39 Stat. 1151.

In the first part of the next decade farmers were suffering considerable losses as a result of the somewhat motley manufacture and distribution of anti-hog cholera serum. The Department of Agriculture apparently felt that the authorization to regulate animal drugs contained in the Food and Drug Act of 1906 did not provide adequate authority to regulate anti-hog cholera serum; the Department procured the passage of the VSTA in response to the anti-hog cholera serum problem. See, Hall v. State, 100 Neb. 84, 158 N.W. 362 (1916). The VSTA, then as now, provided for the regulation of animal biologicals shipped in interstate commerce, with no jurisdiction over biologics merely having a component that had passed through interstate commerce. Responsibility for its administration was placed with the Bureau of Animal Industry, a subdivision of the Department of Agriculture. Appropriations Act of March 4, 1917, Ch. 179, 39 Stat. 1138.

The Food and Drug Act was extensively revised in 1938. Among other changes the jurisdiction over drugs extended to articles intended for use as components in drugs. Act of June 25, 1938, ch. 675, section 201, 52 Stat. 1041, (current version at 21 U.S.C. section 321(g) (1970). It was explicitly stated in the Senate debate on the 1938 Act that no *new*

authority was provided for FDA supervision[2] of *human* biologics.

> *Mr. Vandenberg.* Will the Senator also make a statement for the record as to the effect of this proposed legislation upon biological products, and the possible interference with the existing serum act of 1902, and the existing administration of biological supervision?
>
> *Mr. Copeland.* If the Senator will turn to the last page of the bill, page 56, and read line 6, 7, and 8, he will see that it is provided that the provision of this bill shall not be held to modify or repeal any of the existing laws of the United States, except as provided by paragraph (A) of Section 717. That particular law mentioned by the Senator is not dealt with at all by this bill, and there is no thought of transferring that very well done function of the Public Health Service to the Food and Drug Administration.
>
> *Mr. Vandenberg.* And no new authority over biological products is contained within the bill?
>
> *Mr. Copeland.* Not the slightest.

79 Cong. Rec. 5018 (1935). It is befitting to note that this colloquy occurred at a time when the PHS was in the Department of Treasury and the FDA in USDA. The situation had changed by 1944 when the provisions regulating human biologics were amended.

In 1939 the PHS was transferred from Treasury to the newly created Federal Security Agency. Reorg. Plan No. 1 of 1939, reprinted in 53 Stat. 1423 et seq. The following year the FDA and its functions were transferred to the Federal Security

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[2]Food and Drug regulation had been shifted from the Bureau of Chemistry to a separate Food and Drug Administration within the Department of Agriculture in 1927. *Cf.* Appropriation Act of May 11, 1926, 44 Stat. 515, with Appropriation Act of January 18, 1927, ch. 39, 44 Stat. 991, 44 Stat. 1002.

Agency. Reorg. Plan No. 4 of 1940, reprinted in 54 Stat. 1234 et seq. When the Virus, Serum, and Toxin Act of 1944, dealing with human biologics, was passed Congress made it clear that the FDCA also applied to human biologics. "Subsection (g) is an explicit statement, confirming the present legal situation, that products subject to this section are not exempted from the Federal Food, Drug, and Cosmetic Act, except for the provision of that act relating to the licensing of new drugs." H.R. Rep. No. 1364 78th Cong., reprinted in (1944) U.S. Code & Cong. Serv. 1234; subsection (g) of that Act is now codified at 42 U.S.C. section 262(g). It was felt that the Federal Security Administrator should have the power to recommend seizure under the FDCA when a dangerous product reached the market in spite of the controls exercised by the PHS. S.R. No. 1027, 78th Cong., 2d Sess. (1944). Prior to this nothing appears in Acts of Congress or case history to indicate that the FDCA applied to human biologics. And, indeed, the above quoted discussion between Senators Copeland and Vandenberg in 1935 indicates that the FDCA was not perceived to cover human biologics until sometime after the FDA and PHS were placed in the same agency.

The posture of the USDA was markedly different in 1968 when Congress passed the Animal Drug Amendments to the FDCA from that of the Federal Security Administrator in 1944.[3] The 1968 Amendments were intended to streamline the procedures for the clearance of new animal drugs under the FDCA. See, S. Rep. No. 1308, 90th Cong. (1968). The acting Secretary of Agriculture expressed concern over the possible effect of the 1968 FDCA amendments on the VSTA.

> Virus, Serums, toxins, and analogous products coming within the purview of the Virus-Serum-Toxin Act are all biological products. Historically, the Secretary of Agriculture has regulated such animal biologics, many of which are not used for animals that are a source of human food. Under the provisions of H.R. 3639, these animal biological

[3]All agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare in 1953. Reorg. Plan No. 1 of 1953, reprinted in Appendix to Title 5 of U.S.C.

> products, if considered to be new animal drugs, could not be shipped in interstate or foreign commerce until applications therefor were approved by the Secretary of Health, Education, and Welfare. Also, processing of these applications would be a duplication of work already being performed by the Department of Agriculture and would serve no useful purpose.

H.R. Rep. No. 875, 90th Cong. 10 (1968). Section 392(c) was amended to make it "clear that the act does not supersede the virus, serum, toxin, and analogous provisions of the act of March 4, 1913." H.R. Rep. No. 875, 90th Cong. (1968). The intended effect of section 392(c) is maintenance of the status quo. In the context of regulation of animal biologics the status quo has been regulation by the Secretary of Agriculture under the VSTA.

The FDA has correctly pointed out that great weight should be given to an agency's construction of a statute. The definition of "drug", however, appears to have already been construed as not encompassing animal biologics. As mentioned above, the USDA procured the passage of the VSTA in 1913. At that time the Food and Drug Act of 1906 was administered by the USDA and the definition of "drug" contained in that act was apparently not viewed as encompassing animal biologics. The basic definition of "drug" has not materially changed in the meantime. And the circumstances surrounding the inclusion of the VSTA in section 392(c) indicate that Congress concurred with the USDA interpretation.

Two other factors provide impetus for finding that animal biologics are not subject to regulation by the FDA. First, the FDA concedes that if the Bacterin were produced or shipped in interstate commerce as defined by the VSTA there is no jurisdiction under the FDCA. There is little logical appeal to an interpretation of section 392(c) that would place jurisdiction over the manufacture and distribution of animal biologics when the marketable product crossed state lines in one federal agency and jurisdiction with a totally different federal agency when the identical product is manufactured

and distributed within the boundaries of a single state. Second, there is a bill pending on Congress that would extend the USDA's jurisdiction under the VSTA to intrastate animal biologics. H.R. 4853, 96th Cong. (1978). There seems to be a number of issues involved in the question of federal regulation of intrastate animal biologics. The field has been unoccupied for over sixty years. If there is to be a change in status quo, Congress is a far more appropriate forum for the resolution of these issues.

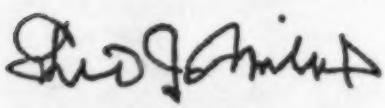
Plaintiff has also questioned the FDA's general authority to obtain a search warrant. This decision makes it unnecessary to resolve that issue.

The defendant's motion to dismiss is therefore denied, and a preliminary injunction will issue against the defendant.

This memorandum decision shall constitute the Court's findings of fact and conclusions of law, pursuant to Rule 52 of the Federal Rules of Civil Procedure.

Done and entered at Sioux Falls, South Dakota, this 21st day of February, 1980.

BY THE COURT:



Chief Judge

APPENDIX D

United States Court of Appeals

FOR THE EIGHTH CIRCUIT

No. 80-1331 September Term, 1981

Grand Laboratories, Inc., *Appellee,*	)	
vs.	)	Appeal from the United States District Court for the District of South Dakota
Patricia Harris, Secretary of Health, Education and Welfare, *Appellant.*	)	

The Court, having considered appellee's petition for rehearing and suggestions for rehearing en banc and being now fully advised in the premises, hereby orders the petition for rehearing and suggestions for rehearing en banc denied.

November 3, 1981

Opposition

Supreme Court, U.S.
FILED
MAR 30 1982
ALEXANDER L. STEVAS
CLERK

No. 81-1428

In the Supreme Court of the United States

OCTOBER TERM, 1981

GRAND LABORATORIES, INC., PETITIONER

v.

RICHARD S. SCHWEIKER, SECRETARY OF HEALTH AND HUMAN SERVICES

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

Whether intrastate animal biologics used to prevent or treat diseases in animals are "[a]rticles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in * * * animals" (21 U.S.C. 321(g)) and thus subject to regulation by the Food and Drug Administration pursuant to the Federal Food, Drug, and Cosmetic Act of 1938, when the components have moved in interstate commerce.

TABLE OF CONTENTS

Page

Opinions below 1

Jurisdiction 1

Statement 2

Argument 4

Conclusion 10

TABLE OF AUTHORITIES

Cases:

American Trucking Association v. *Atchison T. & S. Fe Ry.*, 387 U.S. 397 7

Consumer Product Safety Commission v. *GTE Sylvania*, 447 U.S. 102 ..... 4, 6

FTC v. *Dean Foods Co.*, 384 U.S. 597 7

Kordel v. *United States*, 335 U.S. 345 5

Norwegian Nitrogen Products Co. v. *United States*, 288 U.S. 294 9

Palmer v. *United States*, 340 F. 2d 48, cert. denied, 382 U.S. 903 2

TVA v. *Hill*, 437 U.S. 153 8

Udall v. *Tallman*, 380 U.S. 1 9

United States v. *An Article of Drug* * * * *Bacto-Unidisk* * * *, 394 U.S. 784 ..... 3, 4-5

United States v. *Borden Co.*, 308 U.S. 188 8

United States v. *Detroit Vital Foods, Inc.*, 330 F. 2d 78, cert. denied, 379 U.S. 832 2

Page

Cases—Continued:

United States v. *Dianovin Pharmaceuticals, Inc.*, 475 F. 2d 100, cert. denied, 414 U.S. 830 2

United States v. *Morton Salt Co.*, 338 U.S. 632 9

United States v. *Rutherford*, 442 U.S. 544 ..... 5, 8, 9

United States v. *Sullivan*, 332 U.S. 689 5

Weinberger v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645 9

Zuber v. *Allen*, 396 U.S. 168 9

Statutes:

Animal Drug Amendments of 1968, Pub. L. No. 90-399, 82 Stat. 342 5

Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. 301 *et seq.* 2

Section 201(g), 21 U.S.C. 321(g) 3, 4
Section 201(g)(1), 21 U.S.C. 321(g)(1) 3
Section 902(c), 21 U.S.C. 392(b) 3, 4, 5, 6

Pure Food Act of 1906, ch. 3915, 34 Stat. 768 7

Virus-Serum-Toxin Act of 1913, 21 U.S.C. 151-158 2

Page

Miscelianeous:

49 Cong. Rec. 4146 (1913) 7

124 Cong. Rec. 37213 (1978) 8, 9

21 Fed. Reg. 5577 (1956) 9

Hearings on H.R. 28283 Before the House Comm. on Agriculture, 62d Cong., 3d Sess. 23 (1913) 7

Hearings on H.R. 28283 Before the Senate Comm. on Agriculture and Forestry, 62d Cong., 3d Sess. (1913) 6-7

H.R. Rep. No. 875, 90th Cong., 1st Sess. (1967) 6

Opinion No. 2424, Op. Solic. U.S.D.A. (May 6, 1940) 8

Opinion No. 3800, Op. Solic. U.S.D.A. (Jan. 7, 1942) 6, 9

In the Supreme Court of the United States

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No. 81-1428

GRAND LABORATORIES, INC., PETITIONER

v.

RICHARD S. SCHWEIKER, SECRETARY OF HEALTH AND HUMAN SERVICES

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals en banc (Pet. App. A-1 to A-14) is reported at 660 F. 2d 1288. The opinion of the panel of the court of appeals (Pet. App. A-15 to A-28) is reported at 644 F. 2d 729. The district court opinion (Pet. App. A-29 to A-36) is reported at 488 F. Supp. 618.

JURISDICTION

The judgment of the court of appeals en banc was entered on October 2, 1981, and petitioner's motion for further rehearing en banc was denied on November 3, 1981. The petition for a writ of certiorari was filed on January 29, 1982. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

Animal biologics are products prepared from microorganisms or animal tissues or fluids and used for the prevention or treatment of diseases in animals (Pet. App. A-1). Petitioner Grand Laboratories, Inc., manufactures and distributes animal biologics wholly within the state of South Dakota. Some components of its animal biologics, however, are purchased from out-of-state sources (Pet. App. A-1, A-4 to A-5). The jurisdictional reach of the Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. 301 *et seq.* ("FDCA"), extends to a drug manufactured and distributed within a single state if a component of the drug came from outside the state.[1]

The Virus-Serum-Toxin Act of 1913, 21 U.S.C. 151-158 (VSTA), authorizes the United States Department of Agriculture (USDA) to regulate animal biologics shipped in interstate commerce but does not extend to animal biologics produced and distributed within a single state even if components come from outside the state (Pet. App. A-2 to A-3). Products that are outside the jurisdictional reach of the VSTA, such as those manufactured by petitioner, are referred to herein as "intrastate" animal biologics.

This case arose when petitioner refused to permit inspection of its facilities by the Food and Drug Administration (FDA), and then filed this action seeking both declaratory and injunctive relief. Petitioner argued that the USDA has sole federal regulatory control over animal biologics pursuant to the VSTA and that the FDA therefore lacked authority to inspect its facilities pursuant to the FDCA. The

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[1]See, *e.g.*, *United States* v. *Dianovin Pharmaceuticals, Inc.*, 475 F. 2d 100, 102-103 (1st Cir.), cert. denied, 414 U.S. 839 (1973); *United States* v. *Detroit Vital Foods, Inc.*, 330 F. 2d 78, 81-82 (6th Cir.), cert. denied, 379 U.S. 832 (1964); *Palmer* v. *United States*, 340 F. 2d 48, 49 (5th Cir. 1964), cert. denied, 382 U.S. 903 (1965).

district court agreed and entered a preliminary injunction prohibiting the FDA from inspecting or exercising jurisdiction over petitioner's facilities (Pet. App. A-29 to A-36). A divided panel of the court of appeals affirmed (*id.* at A-15 to A-28). However, on rehearing en banc, the court of appeals reversed (*id.* at A-1 to A-14).

The court noted that all animal biologics fall within the literal definition of a "drug" in the FDCA, 21 U.S.C. 321(g)(1)[2] (Pet. App. A-3). Relying upon this Court's opinion in *United States* v. *An Article of Drug* * * * *Bacto-Unidisk* * * *, 394 U.S. 784 (1969), the court held that the FDCA's definition should be applied literally so as to further the Act's overriding purpose of protecting the public health (Pet. App. A-5 to A-6). The court rejected petitioner's argument that Section 902(c) of the FDCA, 21 U.S.C. 392(b), which provides that the Act shall not "affect or modify" the VSTA, evinces a congressional intent to limit federal regulation of animal biologics to the VSTA. Rather, the court construed the provision literally and concluded that it exempts from FDA scrutiny only those products that are regulated by the USDA under VSTA. Pet. App. A-7. The court recognized that under its interpretation of the literal language of the FDCA some animal biologics would

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[2]21 U.S.C. 321(g)(1) provides:

> The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formularly, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clauses (A), (B), or (C) of this paragraph; but does not include devices or their components, parts, or accessories.

be regulated by the USDA and the rest would be regulated by the FDA depending upon whether the product itself was shipped across state lines. However, the court did not view that result as unreasonable and thus resisted "the temptation to superimpose [its] own ideas of reason and logic on the clear words of a congressional enactment" (*id.* at A-6).[3]

ARGUMENT

The decision of the court of appeals is correct and does not conflict with any decision of this Court or any other court of appeals. Accordingly, further review is unwarranted.

1. "[T]he starting point for interpreting a statute is the language of the statute itself. Absent a clearly expressed legislative intention to the contrary, that language must ordinarily be regarded as conclusive." *Consumer Product Safety Commission* v. *GTE Sylvania,* 447 U.S. 102, 108 (1980). In this case, the express language of the FDCA confers on the FDA regulatory authority over petitioner's products. Section 201(g) of the FDCA, 21 U.S.C. 321(g), defines the term "drug" to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man *or other animals* * * *" (emphasis added).[4] The breadth of this statutory definition is apparent from this Court's decision in *United States* v. *An Article of Drug* * * * *Bacto-Unidisk* * * *, *supra.* In that case, the lower courts had concluded that an antibiotic sensitivity disk was not a drug even though it fell within the literal language of the statutory definition (394 U.S. at 790-791),

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[3]The dissent concluded that the FDA has no jurisdiction over animal biologics. Under its construction of Section 902(c), animal biologics are to be regulated at the federal level exclusively by the USDA. Pet. App. A-9 to A-10.

[4]Even the dissent conceded that this definition encompasses animal biologics (Pet. App. A-9).

reasoning that Congress never intended the term "drug" to be defined so broadly or to encompass a disk that could be classified as a "device" and thus regulated under other, exclusive provisions of the FDCA. *Ibid.* This Court reversed and expressly rejected the lower courts' reasoning. Noting the broad language of the FDCA as well as its remedial purpose, this Court held that "Congress fully intended that the Act's coverage be as broad as its literal language indicates * * *" (394 U.S.C. at 798). Thus, petitioner's attempt here to disregard the literal language of the FDCA's definition of the term "drug" is inconsistent with this Court's approach in *Bacto-Unidisk*. See also *United States* v. *Rutherford*, 442 U.S. 544 (1979).[5]

The decision below is also supported by the literal language of Section 902(c) of the FDCA, 21 U.S.C. 392(b). That provision expressly defines the relationship between the FDCA and the VSTA. Section 902(c) provides that "[n]othing contained in [the FDCA] shall be construed as in any way affecting, modifying, repealing, or superseding the" VSTA.[6] Thus, those animals biologics subject to the

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[5]Petitioner provides no persuasive rationale for departing from the clear teaching of *Bacto-Unidisk*. It suggests (Pet. 12-14) that stronger evidence of congressional intent is required here because of the impact of this case on federal-state relations. However, the cases upon which petitioner relies are inapposite. Decisions construing certain federal criminal statutes narrowly so as not to disturb the historical federal-state relationship in that field have little relevance to the construction of the term "drug" in the FDCA. The long-standing federal involvement in food and drug regulation belies petitioner's claim (Pet. 13) that FDA is seeking to intrude into an "area of commerce that has traditionally been regulated exclusively by the states." Moreover, in *United States* v. *Sullivan*, 332 U.S. 689 (1948), and *Kordel* v. *United States*, 335 U.S. 345 (1948), this Court specifically rejected attempts to give the FDCA's interstate commerce requirement a narrow construction that would have significantly decreased federal regulation of drugs, thereby endangering public safety.

[6]The reference to the VSTA was added to Section 902(c) when Congress enacted the Animal Drug Amendments of 1968. The USDA supported this provision in order to avoid duplicative regulation of

VSTA are not also subject to the FDCA, because such regulation would affect, modify, or supersede the VSTA. By contrast, animal biologics not controlled by the VSTA are subject to the FDCA, because they come within that Act's definition of the term "drug." FDA regulation of products in the latter group would not affect, modify, or supersede the VSTA.

If animal biologics were not drugs, Congress would have had no reason to refer to the VSTA in Section 902(c) because the FDCA then could not have possibly affected the VSTA. Since Congress saw a need to refer to the VSTA in Section 902(c), however, it must have understood that animal biologics are drugs and that, without such a reference, animal biologics subject to the VSTA would have been subject to duplicative regulation under the FDCA.

2. Petitioner contends (Pet. 14) that the court of appeals' reliance on the literal language of the Act ignores "the interrelationship of the several statutes involved and the relevant legislative histories and prior administrative interpretations in question." There is, however, no "clearly expressed" legislative history inconsistent with the literal language of the Act (*Consumer Product Safety Commission* v. *GTE Sylvania, supra,* 447 U.S. at 108) and no prior, contrary administrative interpretations.

a. The VSTA was passed in 1913 because Congress believed that animal biologics should be subject to clearance before they were placed on the market. See, *e.g., Hearings on H.R. 28283 Before the Senate Comm. on*

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animal biologics. See H.R. Rep. No. 875, 90th Cong., 1st Sess. 9-10 (1967). The USDA has long believed that animal biologics are encompassed by the statutory definition of the term "drug" in the FDCA. See Opinion No. 3800, Op. Solic. U.S.D.A. (Jan. 7, 1942). (A copy of this opinion is appended to the government's reply brief in the court of appeals.)

Agriculture and Forestry, 62d Cong., 3d Sess. 68 (1913); *Hearings on H. R. 28283 Before the House Comm. on Agriculture*, 62d Cong., 3d Sess. 23 (*House Hearings*) (1913); 49 Cong. Rec. 4146 (1913) (Remarks of Sen. Cummins). Nothing in the legislative history suggests that animal biologics were not already subject to federal regulation pursuant to the Pure Food Act of 1906, ch. 3915, 34 Stat. 768. The legislative history of the VSTA emphasizes the need to stop worthless or harmful animal biologics from entering the marketplace. The Pure Food Act did not accomplish this congressional objective because it authorized remedial judicial action only after a violation had been detected.[7] Thus, the fact that Congress decided to subject animal biologics to additional federal regulation under the VSTA is not evidence of a legislative intent to exclude animal biologics from regulation under the previously enacted Pure Food Act.

Contrary to petitioner's suggestion (Pet. 14), Section 902(c), defining the relationship between the FDCA and VSTA, is not proof that Congress intended to exempt all animal biologics. If anything, the language indicates that Congress did not intend a total exemption. It is noteworthy that petitioner has cited no legislative history expressly stating that animal biologics are not drugs within the meaning of the FDCA or that the VSTA was intended by Congress to be the sole means by which the federal government regulated animal biologics. In the absence of any such legislative history, the court of appeals properly refused to

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[7]The fact that the USDA, which at that time administered the Pure Food Act, sought more extensive regulatory authority over animal biologics is not proof that it then lacked any authority over those products. Indeed, this Court has consistently refused to construe an agency request for new legislation clarifying its authority as an admission that it lacks the authority in question. *FTC* v. *Dean Foods Co.*, 384 U.S. 597, 610 (1966). See also, *e.g.*, *American Trucking Association* v. *Atchison T. & S. Fe Ry.*, 387 U.S. 397, 417-418 (1967).

create an unintended gap in federal regulation by ignoring the FDCA's literal language.[8] Rather, the court recognized that where two federal statutes cover the same subject matter, the correct approach to statutory construction is to give full effect to both, if possible. *TVA* v. *Hill*, 437 U.S. 153, 189-190 (1978); *United States* v. *Borden Co.*, 308 U.S. 188, 198 (1939). In this case, a literal construction of both the FDCA and the VSTA gives full effect to both and does not produce "results so manifestly unreasonable that they could not fairly be attributed to congressional design * * *" (*United States* v. *Rutherford, supra*, 442 U.S. at 555).[9]

b. Contrary to petitioner's contention (Pet. 16), there are no "long-standing administrative interpretations of the relevant statutory provisions" that are inconsistent with the court of appeals' decision.[10] In fact, both the FDA and

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[8]It has been reported that one-third of the states have no regulation of animal biologics and that most of the others merely require registration of such prodicts without also mandating quality control. See 124 Cong. Rec. 37213 (1978) (Remarks of Rep. Wampler). That there is a potential health problem is apparent from the testimony given in this case indicating that petitioner's products may not be effective for their intended uses (Tr. 77-78, 211-214). ("Tr." refers to the transcript of the hearing in the district court.)

[9]The fact that both the FDA and the USDA have jurisdiction over animal biologics under the court of appeals' interpretation does not indicate that the court's interpretation is unreasonable. It is not uncommon for more than one federal agency to regulate in the same field pursuant to concurrent or complementary statutory authority. For example, both FDA and the Federal Trade Commission regulate promotional materials and claims made for over-the-counter drugs and some foods, and both the FTC and the Department of Justice administer the nation's antitrust laws.

[10]The only administrative interpretation petitioner cites (Pet. 9) is Opinion 2424, Op Solic. U.S.D.A. (May 6, 1940). However, that 1940 opinion merely interprets Section 902 of the FDCA to mean that the statutes listed in that Section should be regarded as "paramount and exclusive in the means of control over the articles *falling within their respective scopes*" (emphasis added). This case does not involve "articles falling within" the scope of the VSTA. Rather, it involves intrastate

the USDA have long agreed that intrastate animal biologics are encompassed within the statutory definition of the term "drug" in the FDCA. The USDA issued an administrative opinion in 1942 stating that animal biologics are drugs,[11] and a 1956 FDA regulation (21 Fed. Reg. 5577 (1956)) exempted USDA-regulated biologics from FDA requirements. That regulation would be superfluous under petitioner's statutory construction.[12] Thus, the decision of the court of appeals is consistent with the long-standing view of both the FDA and the USDA and is supported by prior decisions of this Court holding that the views of an administrative agency concerning the scope of its statute are entitled to substantial deference. See, *e.g.*, *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653-654 (1973); *United States* v. *Rutherford, supra*, 442 U.S. at 553-554; *Udall* v. *Tallman*, 380 U.S. 1, 16 (1965). Such deference is particularly appropriate where, as here, the agency had a role in drafting the statutory language. *Zuber* v. *Allen*, 396 U.S. 168, 192 (1969); *Norwegian Nitrogen Products Co.* v. *United States*, 288 U.S. 294, 315 (1933).

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animal biologics that are subject to the FDCA but are not within the scope of the VSTA. Thus, consistent with the Solicitor's opinion, the court of appeals correctly held that intrastate animal biologics are subject to the FDCA.

[11]See Opinion No. 3800, Solic. U.S.D.A. *supra*.

[12]Petitioner relies on alleged agency inaction as a basis for refusing to apply the statute. Yet it is clear that agency inaction alone is insufficient to sustain a finding that the agency lacks the power to act. See, *e.g.*, *United States* v. *Morton Salt Co.*, 338 U.S. 632, 647-648 (1950). Moreover, reliance on alleged agency inaction is particularly inappropriate in this case because it is only in recent years that technological and scientific advances have led to expanded production and use of animal biologics and to an increase in the number of intrastate animal biologics manufacturers. See 124 Cong. Rec. 37213 (1978) (Remarks of Rep. Wampler); Tr. 28.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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Amicus Brief

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No. 81-1428

IN THE

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OCTOBER TERM, 1981

GRAND LABORATORIES, INC.,
Petitioner,

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RICHARD S. SCHWEIKER, SECRETARY
OF HEALTH AND HUMAN SERVICES,
Respondent.

BRIEF AMICUS CURIAE IN SUPPORT OF PETITION FOR CERTIORARI ON BEHALF OF

POULTRY HEALTH LABORATORIES, INC., CUSTOM BIOLOGICS, INC., SCOTT BIOLOGICS, INC., NORTH CAROLINA VACCINE CO., TEXAS VET LAB, INC., DR. MAYFIELD LABORATORIES, INC. POULTRY ANTIGEN LABORATORIES, LANGSTON LABORATORIES, INC. SUNNYMEAD POULTRY RANCH, BIO-TECH, INC. INLAND EMPIRE POULTRYMEAD INC., EGG WEST INC. DR. MARION HAMMARLUND, D.V.M., GROSS EGG RANCH, INC. DR. EILEEN M. OLMSTEAD, D.V.M., DR. ROBERT O. OLSEN, D.V.M. CALIFORNIA WOOL GROWERS ASSOCIATION

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES ii

STATUTES AND REGULATIONS v

MISCELLANEOUS vi

STATEMENT OF INTEREST 1

REASONS THE WRIT SHOULD BE GRANTED

I. THE ADVANTAGES OF AUTOGENOUS AND LOCALLY PRODUCED BACTERIAL AND VIRAL VACCINES OVER INTERSTATE VACCINES 2

II. THERE IS NO PUBLIC HEALTH RISK WITH INTRASTATE ANIMAL BIOLOGICS WHICH WARRANTS A LIBERAL INTERPRETATION OF 21 U.S.C. § 321(g)(1) 8

III. COURTS OF APPEAL DECISIONS CONFLICT WITH EACH OTHER 11

IV. INTRASTATE ANIMAL BIOLOGICS ARE NOT WITHIN THE MEANING OF 21 U.S.C. § 321(g)(1) 12

V. PETITIONER HAS NEVER CONCEDED THAT INTRASTATE ANIMAL BIOLOGICS ARE DRUGS WITHIN THE MEANING OF 21 U.S.C. § 321(g)(1) 17

VI. THE TENTH AMENDMENT TO THE U.S. CONSTITUTION PRECLUDES FDA JURISDICTION OVER INTRASTATE ANIMAL BIOLOGICS BASED ON THE COMMERCE CLAUSE 18

CONCLUSION 22

TABLE OF AUTHORITIES

Cases: **Pages**

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Stafford v. Wallace, 258 U.S. 495 (1921) 19

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STATUTES: **Page**

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(CH 814, 49 STAT 977)
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§ 201(f), 21 U.S.C § 321 (f) 16
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42 U.S.C. § 262 *et seq.* 11, 12

Virus, Serum, Toxin Act of 1902,
CH 1378, 32 STAT 728 13

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21 U.S.C. §§ 151-158 ..... 14, 15

REGULATIONS:

9 C.F.R. § 102.4 7
9 C.F.R. § 102.5 7
9 C.F.R. § 103 7
9 C.F.R. § 106(b) 7
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No. 81-1428

IN THE

Supreme Court of the United States

OCTOBER TERM, 1981

GRAND LABORATORIES, INC.,
Petitioner,

v.

RICHARD S. SCHWEIKER, SECRETARY
OF HEALTH AND HUMAN SERVICES,
Respondent.

BRIEF AMICUS CURIAE IN SUPPORT OF PETITION FOR CERTIORARI ON BEHALF OF

POULTRY HEALTH LABORATORIES, INC., CUSTOM BIOLOGICS, INC., SCOTT BIOLOGICS, INC., NORTH CAROLINA VACCINE CO., TEXAS VET LAB INC., DR. MAYFIELD LABORATORIES, INC. POULTRY ANTIGEN LABORATORIES, LANGSTON LABORATORIES, INC. SUNNYMEAD POULTRY RANCH, BIO-TECH, INC. INLAND EMPIRE POULTRYMEN, INC., EGG WEST, INC. DR. MARION HAMMARLUND, D.V.M., GROSS EGG RANCH, INC. DR. EILEEN M. OLMSTEAD, D.V.M., DR. ROBERT O. OLSEN, D.V.M. CALIFORNIA WOOL GROWERS ASSOCIATION

STATEMENT OF INTEREST

The majority of the parties on this amicus curiae brief are intrastate manufacturers of animal biologics (e.g., vaccines composed of killed bacteria or viruses) who sell these autogenous and locally produced homologous vaccines to farmers and ranchers.[1] These vaccines are generally

[1] Poultry Health Laboratories, Inc. (California), Custom Biologics, Inc. (Kentucky), North Carolina Vaccine Co. (North Carolina), Texas Vet Lab. Inc., (Texas), Dr. Mayfield Laboratories, Inc. (Iowa), Langston Laboratories,Inc. (Kansas). Scott Biologicals, Inc. (California), Bio-Tech, Inc. (Tennessee), and Poultry Antigen Laboratories (California).

recognized by veterinarians as the most effective method of controlling animal disease. The remaining parties on this *amicus curiae* brief are veterinarians or poultry and livestockmen who utilize these intrastate animal biologics, in particular, customized (autogenous) products.[2]

The *amicus* have a special interest here because the immediate effect of the Eighth Circuit opinion will be the severe disruption of their intrastate business and severe restriction of the availability of these necessary vaccines. Intrastate manufacturers will have to comply with the FDA animal drug regulations prior to selling these vaccines. The animal drug regulations involve a process that can take years and the anticipated additional costs will have the effect of forcing intrastate manufacturers out of business.

The additional layers of FDA regulations, which are applicable because of the Eighth Circuit decision, are inconsistent with the intent of Congress to leave the regulation of these products to the States and the regulatory process will provide no benefits to the public to offset the excessive economic costs.

REASONS THE WRIT SHOULD BE GRANTED

I. THE ADVANTAGES OF AUTOGENOUS AND LOCALLY PRODUCED BACTERIAL AND VIRAL VACCINES

The basic concept of vaccination of humans and animals against infectious diseases is derived from the observations of Dr. Edward Jenner, who in 1796 used cowpox crusts, *vaccina variolae*, to protect against the severe infection of smallpox.[3]

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[2]Inland Empire Poultrymen, Inc. (California); Dr. Robert D. Olsen, D.V.M. (California); Dr. Eileen M. Olmstead, D.V.M. (California); Dr. Marion Hammarlund, D.V.M., (California); Sunnymead Poultry Ranch (California); Egg West, Inc. (California); Gross Egg Ranch, Inc., (California; and California Wool Growers Association (California).

[3]Suspensions of killed, intact bacteria used for vaccination are frequently referred to as vaccines. However, if prepared from bacteria, they are more correctly termed bacterins. The term vaccine is properly restricted to smallpox vaccine since it is derived from cows (latin, vacca = cow). Vaccine is commonly used to denote any immunizing antigens or agents, and is so used here. M. FROBISHER, R.D. HINSDILL, K.T. CRABTREE, and G.R. GOODHEART, *FUNDAMENTALS OF MICROBIOLOGY*, 396 (9th ed. 1974).

Louis Pasteur subsequently used attenuated and killed bacteria to protect animals from chicken cholera and anthrax, as well as a modified rabies virus for vaccination against rabies.[4] The protection or host resistance to infectious disease induced by vaccination is equivalent to that immunity induced by active bacterial or viral infections.

Vaccination is based on the well established immunologic principle that mammals recognize what is foreign, i.e., "non-self." Each bacteria or virus, like each mammalian cell, possesses unique "self" characteristics termed antigens; an organism's "self" antigen mosaic, or fingerprint, distinguishes it from another organism.[5] Immunity occurs when bacterial atnigens are injected into mammals who recognized the bacterial antigens as "non-self" and develop resistance to subsequent exposure to infectious bacteria possessing identical or similar antigens. Thus, the ultimate purpose of any vaccine is to stimulate the host's natural immune system to resist any subsequent infections by bacteria or viruses having similar or identical antigens. The efficacy of any vaccine is therefore very dependent upon selection of the proper antigen(s) for use as the vaccinating agent.

Bacterial vaccines, bacterins, are prepared by procedures similar to those originally described by Louis Pasteur.[6] Briefly, an organism is isolated from a diseased animal and grown in bulk liquid or agar media. After growth for 24-48 hours, bacteria are separated from the media, washed with physiological salt solution and concentrated by centrifugal

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[4]R. MANDE, "BACTERIAL VACCINES," 30 *ANNALES NESTLE*, (1973).

[5]Antigenic differences between bacteria allow for their classification into groups: each bacteria belongs to a strain (subgroup), each strain to a species, each species to a genus, and each genus to a family. R.E. BUCHANAN and N.E. GIBBONS, (Editors), *BERGEY'S MANUAL OF DETERMINATIVE BACTERIOLOGY*, 370 (8th ed., 1974). Although a family of bacteria, e.g., *Pasteurella*, share common antigens, its individual strains are distinguishable by unique "self" antigens, termed serotypes. For example, *Pasteurella multocida*, the infectious agent in animal cholera can be subdivided by these antigen differences into five serotypes — A, B, C, D, and E. Id. at 370.

[6]supra at note 4.

force. The bacteria are then killed by heat or chemicals and frequently mixed with adjuvant[7] which non-specifically increases the strength and duration of the immunity induced.[8]

Vaccines prepared using bacteria or viruses isolated from an individual animal, or from a diseased herd, which one wishes to protect or to treat prophylactically with that vaccine, are referred to as autogenous (autologous) vaccines.[9] Those vaccines prepared from commercially available organisms, which presumably are similar, are referred to as homologous vaccines.[10]

The problem of selecting the proper strain or serotype of bacteria or virus for vaccine production is relevant to the legal issue before the court in terms of public health. We believe that intrastate animal biologics manufacturers need sufficient flexibility to produce vaccines containing appropriate strains or serotypes of bacterium or viruses responsive to local state needs. Numerous examples can be cited from scientific literature to substantiate the need for

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[7]Adjuvants are non-antigenic materials - aluminum hydroxide, mineral oil, etc. - which non-specifically increase the strength and duration of the immunity induced by slowly releasing over an extended period antigens from the site of vaccination.

[8]W.J. HERBERT, *VETERINARY IMMUNOLOGY*, 216 (1970).

[9]Id. at 197.

[10]Homologous vaccines prepared using bacterial isolates from the local community tend to be more efficacious than those prepared with isolates purchased from commercial sources. The increased efficacy is derived from the fact that local community isolates may share more antigens with the actual infectious bacteria in the community. L.E. HANSON, Q.N. TRIPATHY & A.H. KILLENGER, 6 *J. AM. VET. MED. ASS'N.*, 1235 (1972).

locally produced vaccines.[11] The advantages of autogenous and local homologous vaccines are well recognized in the veterinarian and livestock communities as exemplified by the findings of Hanson *et al.*

> Vaccination with leptospiral bacterins has become the most effective method of leptospriosis control in a susceptible herd, using specific bacterins against the serotypes prevalent in the area.

6 *J. AM. VET. AM. ASS'N.* 1235 (1972).

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[11]A vaccine against fowl cholera using a serotype of *Pasteurella multocida* was shown to be 100% effective in preventing fowl cholera due to that serotype, but only 70% as effective against other *Pasteurella multocida serotypes which produce disease. J.I. DUFFY, VACCINE PREPARATION TECHNIQUES,* 208 (1980). *Pasteurella multocida* serotypes A and C cause fowl cholera more frequently than serotypes B and D. *METHODS FOR EXAMINING POULTRY BIOLOGICS FOR IDENTIFYING AND QUANTIFYING AVIAN PATHOGENS,* NATIONAL RESEARCH COUNCIL, NATIONAL ACADEMY OF SCIENCE (1971). Commercial interstate vaccines for animal cholera usually employ only one bacterial serotype. C.E. ARONSON, *VETERINARY PHARMACEUTICALS AND BIOLOGICALS 1980/1981,* (1981).

M.M. BORDER, & B.D. FIREHAMMER, 4 *AM. J. VET. RES.,* 746 (1980) studied the efficacy of a vaccine against bovine campylobacterosis, caused by *Campylobacter fetus.* Although all three serotypes of *C. fetus,* i.e., subspecies *fetus, intestinlis,* and *jejuni,* possess a common antigen, immunization of a herd with one serotype only protects against that serotype and not against the two others.

J.H. GRAVES, P.H. McKERCHER and J.J. CALLIS, 33 *AM. J. VET. RES.,* 765 (1971) demonstrated that protection of cattle against viral foot-and-mouth disease is highly dependent upon the subtype of virus used for vaccination. Cattle immunized with subtype O were still susceptible to subtypes A and C which also cause foot and mouth disease.

W.H. MOON, 42 *AM. J. VET. RES.,* (1980) reported that vaccination of swine with a specific strain of *E. coli,* protected only for that strain and did not offer cross-protection against infection by other strains of *E. coli.*

J.M. NERVIG, H.C. ELLINGHAUSEN, and M.Z. CARDELLA, 38 *AM.J.VET. RES.,* 1421 (1976) demonstrated that vaccination with *Leptospira interrogans* serotype *szwajizak* did not protect against infection with *L. interrogans* serotype *hardjo.* Since there are over 130 different serotypes of *Leptospira,* vaccination of animals with one serotype offers little or no protection against infection by other serotypes.

Autogenous or locally produced homologous vaccines offer the local farmer an immediate source of assistance. In contrast, commercial interstate vaccines to be "universally" effective, as evidenced by the examples cited in footnote 11 must contain all the anticipated serotype antigens in sufficient quantity to stimulate immunity.[12] The production of "universal" polyvalent serotypic vaccines is difficult since the threshold level for the induction of immunity against each serotype antigen can vary.[13] Because of these problems, autogenous or locally produced homologous vaccines many times are the prophylactic therapy of choice since they are more likely to contain the bacteria or virus causing disease within the local community. One could characterize such vaccines as essentially customized products prepared to meet the needs of the local community.

It is appropriate for the Court to take notice that the preparation of bacterial vaccines is a prophylactic therapy which experts recognize as efficacious. Prior to the discovery and wide availability of antibiotics, vaccines were used extensively to treat persistant human illnesses. The FDA has not faulted the methodology used to produce these animal biologics, but sought to require intrastate manufacturers to demonstrate the efficacy and safety of their vaccines.[14]

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[12]I.R. TIZARD, *AN INTRODUCTION TO VETERINARY IMMUNOLOGY*, 198 (1977).

[13]W.J. HERBERT, *VETERINARY IMMUNOLOGY*, 187 (1970).

[14]Testimony at the trial supported the safety and effectiveness of the Grand Laboratories product in question. Dr. Bernard W. Donelan, a veterinarian, testified he used the product in a 600 pig-sow controlled experiment and found it effective, page 142, ln. 1-17; Dr. Robert P. Ellis, Dept. Microbiology, College of Vet. Med. Colo. State Univ., testified that the vaccine in question would be useful,page 184, ln. 12-24; William C. Buller, hog farmer (12-15,000 hogs'year) and President of the U.S. Pork Producers Ass'n., testified that Grand Laboratories prepared custom autogenous vaccines for his herds that were effective, page 128, ln. 7-9 and page 132, ln. 6-12; and Clint R. Roberts, Secretary of Agriculture of South Dakota testified his office has not received any complaints about Grand Laboratories' products. FDA testimony by Dr. Richard F. Ross, a research veterinarian, Iowa State Univ., that this product was not effective, was impeached by his own published article, *AM. J. VET. RES.* (Jan. 1977) in which he stated that a vaccine made with *Streptococcus equisimilus* might be useful, page 175, ln. 5-16.

Ironically, intrastate manufacturers who use local isolates of the disease-causing organism in the community will be subjected to a heavier FDA regulatory burden of proof, than interstate manufacturers licensed under the U.S.D.A.[15]

The Court in considering the Petition for a Writ of Certiorari will want to be cognizant of the practical effects of its decision. Denial of the Petition would have the immediate effect of allowing FDA to terminate production of all autogenous or local homologous vaccines until such time as these producers could demonstrate safety and efficacy. The economic burden of complying with applicable FDA regulations would make the cost of such intrastate vaccines prohibitive and force most, if not all, intrastate manufacturers out of business. Intrastate manufacturers currently sell their vaccines for $10 to $100 per 100 milliliters. These are used in quantitites of 1 to 5 ml. per vaccination per animal. This amount is totally insufficient to allow any recovery of costs incurred by compliance with FDA testing, licensing and manufacturing regulations.[16] Under current

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[15]USDA regulations require animal biologic manufacturers to obtain an establishment license (9 C.F.R. § 102.4) and a product license for each biologic (9 C.F.R. § 102.5). All biologics must be manufactured according to their published standard (9 C.F.R. § 113) and new products developed pursuant to 9 C.F.R. § 103. USDA regulations were developed specifically for animal biologics, in particular, their immunologic characteristics, and have flexibility to meet emergency animal disease situations (9 C.F.R. § 106(b)); whereas, FDA new animal drug regulations (21 C.F.R. § 514) are suited to regulate products in terms of their pharmacologic and toxicologic effects.

[16]If animal biologics are determined to be "drugs", intrastate manufacturers will be required under 21 C.F.R. § 511 to file a research application, *Investigational New Animal Drug Application*, for each vaccine to permit them to perform clinical studies to demonstrate safety and efficacy. The results of such studies must then be presented in a *New Animal Drug Application*, 21 C.F.R. § 514. When food producing animals are the intended recipients of any new drugs, FDA requires radioactive label tracing studies which show the residual levels of the drug in such animals, the lifetime feeding experiments, etc. To pass the current regulatory guideline the manufacturer must show that less than 1 person in a million will possibly be affected (at the 99% confidence level). The cost of such experiments is prohibitive and easily in excess of $400,000-$600,000. The FDA regulations concerning licensing and testing of animal drugs are inappropriate and inapplicable to animal biological products. This excessive economic cost of the animal drug regulations strongly suggests that FDA has not considered their application to biological products.

FDA drug regulations, the commercial availability of autogenous or local homologous vaccines to farmers and livestock breeders would take years, and not days as is now the case.

II. THERE IS NO PUBLIC HEALTH RISK WITH ANIMAL BIOLOGICS WHICH WARRANTS A LIBERAL INTERPRETATION OF 21 USC §321(g)(1).

In reversing the District Court, the Eighth Circuit Court of Appeals gave a very liberal and broad interpretation to the meaning of "drug" as defined by 21 U.S.C. §321(g)(1). This liberal interpretation by the Court of Appeals was based on its perception of the holding in *U.S. v. An Article of Drug . . . Bacto-Unidisk,*

> that remedial legislation such as the Food, Drug and Cosmetic Act is to be given a liberal construction with the Act's overriding purpose to protect public health.

394 U.S. 784, 789 (1969).

The result of the liberal construction given by the Eighth Circuit Court of Appeals, and by other courts,[17] to *Bacto-Unidisk,* is that FDA may unilaterally broaden its jurisdiction where it perceives a threat to public health. The dissent by Judges Heaney and Bright after the *en banc* appeal argued correctly that *"Bacto-Unidisk* and the policy it expouses, however, simply do not apply to the present case." *Grand Laboratories, Inc. v. Patricia Harris,* 660 F.2d 1288, 1295 (8th Cir. 1981).

Grand Laboratories can be distinguished from *Bacto-Unidisk* by the lack of reasonably perceived public health risk. In *Bacto-Unidisk,* the FDA perception that the proper assessment of bacterial sensitivity to antibiotics is critical to subsequent successful human therapy was

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[17] *U.S. v. An Article of drug ... OVA II,* 414 F. Supp. 660 (N.J. 1975), *aff'd,* 535 F.2d 1248 (2nd Cir. 1976); *National Nutritional Foods Ass'n v. Weinberger,* 512 F.2d 688, (2nd Cir., 1975).

reasonable. We strongly suggest that FDA's perception of a similar public health risk in *Grand Laboratories* is unreasonable, since it is difficult and far fetched to conceptualize a life-and-death risk to the public from the use of animal biologics in animals.

FDA's statement of a risk to humans or public health is the bald assertion that "FDA determined the public health interests require it to exercise its jurisdiction over the growing field of 'intrastate' animal biologics" and that the Court should not "second guess FDA's medical judgment in determining whether or not a given program of regulation is desirable."[18] In the District Court hearing, FDA evidence questioning the efficacy of the Grand Laboratories' product at issue was limited and countered by Petitioner's witnesses. *Supra*, note 14.

The amici believe that FDA's perception of a health risk should be governed by the standard of reasonableness first articulated by this Court in *Lawton v. Steele*, 152 U.S. 133, 137 (1894) and followed in *Goldblatt v. Hemstead*, 369 U.S. 590 (1962). This standard states that to justify the use of police powers on behalf of the public, it must be evident that the interests of the public require such regulation. Thus,any determination by FDA based on the efficacy of only one product is inequitable and an unreasonable basis to now regulate all intrastate animal biologics as drugs. This standard of reasonableness demands that FDA demonstrate, at the very least, a pattern of problems within the entire industry which threatens human public health sufficient to warrant a liberal interpretation of 21 U.S.C. § 321(g)(1).

Animal biologics, in fact, present no real threat to public health in terms of safety. A recognized advantage of heat or formalin killed bacteria or viral vaccines is that they possess no residual virulence and, once killed, they do not revert to infectious organisms. Occassionally such vaccines may induce mild irritations at the site of vaccination which are localized and usually of short duration.

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[18]Appelant's brief at 28-30, *Grand Laboratories, Inc* v. *Patricia Harris*, 660 F.2d 1288 (8th Cir., 1981).

In terms of efficacy, if a vaccine fails to induce "any" immunity, or more likely, induces immunity to the wrong or non-cross-reacting organism, the quarantined animals would succumb to the disease; such "vaccine failures" would be self-limiting. Such animals are properly destroyed under other state laws and accepted animal husbandry practices.

Ironically, animals immunized with interstate vaccines produced with common laboratory strains of commercially available bacteria run a much greater risk of being either poorly immunized or not immunized. As previously discussed, interstate vaccines are more likely to contain bacterial serotypes or strains different from those which actually cause the disease in local animals. *Supra*, note 11.

FDA's expertise does not allow it to keep on extending its jurisdiction to other articles or items without having the Court review whether Congress intended that the specific article or item was within the meaning of the authorizing language. Even an emergency situation, akin to an extremely serious public health problem, "may not call into life a power which has never lived, nevertheless emergency may afford a reason for the exertion of a living power already enjoyed. *Wilson v. New*, 243 U.S. 332, 348 (1917)," cited in *National League of Cities v. Usery*, 426 U.S. 833, 853 (1976).

Although *National League of Cities* overruled *Maryland v. Wirtz*, 392 U.S. 183 (1968), the rational basis test articulated in *Maryland v. Wirtz* is still a relevant tool that may be applied in determining if the expert agency (FDA) has reason to exert a power already enjoyed. The rationale basis test, which the Court applied to the instrusion of the federal government into state activities is also consistent with the *Lawton* and *Goldblatt* standard of reasonableness.

We urge the Court to further define what it decided in *Bacto-Unidisk*. We believe the Court did not intend to give FDA carte blanche authorization to extend its jurisdiction, beyond its specific statutory authority and in contradiction to carefully consider grants of authority and specific exemptions from Congress, unless a valid need to protect public health exists, i.e., a rational basis or reasonableness.

Failure to grant Certiorari will in effect authorize FDA, as well as other federal agencies, to continue relying on *Bacto-Unidisk* to retrospectively legitimatize their unilateral actions and provide a judicially sanctioned vehicle to continue the extension of federal jurisdiction without legislative concurrence. The Court in *Grand Laboratories* has the opportunity to establish more precise guidelines for the construction of FDA jurisdiction by lower courts and the agency.

III. COURTS OF APPEAL DECISIONS CONFLICT WITH EACH OTHER

Although the Petition for Certiorari does not set forth a direct conflict between Courts of Appeal, a definite conflict does exist.

The Fifth Circuit in *Blank v. U.S.*, 400 F.2d 302 (5th Cir. 1968) held that citrated whole blood, which it found was a "drug," was not within the definition of "analogous products," a definition in the Public Health Service Act, 42 U.S C. § 262. Congress later amended 42 U.S.C. § 262 to include "blood, blood components or derivatives" to show its legislative intent that citrated whole blood in the broad sense, at least for regulatory purposes, is a biologic, Pub. L. 91-515, 84 STAT. 1308, Oct. 30, 1970.

If a drug is not a biologic until Congress makes it so, then the converse is just as true—an animal biologic is not an animal drug until Congress makes it so.

Blank v. U.S. at 304, is also instructive as to any analogy concerning similar "intended uses." This Court held that even though blood was a common source of numerous products, that fact alone, in the primary sense of analogy, does not make the products similar or corresponding. Thus, products with the same intended uses as defined by 21 U.S.C. § 321(g)(1), the treatment of disease in animals, are not necessarily similar or corresponding.

In its *Grand Laboratories* Eighth Circuit brief FDA argued that an article intended for use in "other animals" is a drug and since animal biologics were used for the prevention or

treatment of disease in animals, they are drugs. Logically, bacterins intended for the treatment of animals could be "drugs." But, while the statutes defining the jurisdiction of FDA and USDA are not necessarily logical, they are quite clear. Animal biologics were intended to be excluded from FDA's jurisdiction.

It is within the full discretion of courts to reverse, modify, explain or distinguish its prior decisions. When doing so, courts are sensitive to the need to be instructive and provide guidance to lower courts. In *Parke-Davis & Co. v. Stromsodt*, 411 F.2d 1390, 1393 (8th Cir. 1969), the court held that

> Pertussis vaccine is a 'biological' as opposed to a drug within the framework of federal statutes and regulations (42 U.S.C. § 262 *et seq.*). Its licensing and regulation are therefore under the Department of Health, Education and Welfare (H.E.W.) rather than through the Food and Drug Administration (F.D.A.).

If an admitted human biological was not a drug in 1969 when the Eighth Circuit decided *Parke-Davis*, a products liability case, then it must have become a drug by itself following that court's decision in *Grand Laboratories*. The Eighth Circuit failed to provide proper guidance as to whether they intend only to apply *Parke-Davis* as the rule in product liability cases, whereas *Grand Laboratories* is the rule in regulatory enforcement actions; thus, there is a conflict within the Eighth Circuit opinions.

The existence of a direct conflict between the Fifth Circuit holding in *Blank v. U.S.* and the Eighth Circuit holding in *Grand Laboratories*, along with need to clarify the holding in *Parke-Davis*, are compelling reasons why a Writ of Certiorari should be granted in this case.

IV. ANIMAL BIOLOGICS ARE NOT DRUGS WITHIN THE MEANING OF 21 U.S.C. § 321(g)(1)

In construing a statute, one begins by utilizing the "plain meaning" of the language used by Congress when it enacted the statute. *General Electric v. Gilbert*, 429 U.S. 142, 145

(1976). The "plain meaning" is that consistent with the contemporaneous interpretation of the language evident before or shortly after the passage of an Act. In *U.S. v. National Association of Security Dealers*, 422 U.S. 674, 715-719 (1975), the Court found the meaning of the statutory language by examining congressional hearings, comments on proposed rules, agency opinions or memoranda and other sources.[19]

Congress, when enacting the revised Federal Food, Drug & Cosmetic Act of 1938, intended that a clear definitional distinction exist between the two types of products. During committee hearings, Senator Copeland stated that the proposed Federal Food, Drug & Cosmetic Act did not contain new authority for FDA over biologics.[20] If Congress intended them to be definitionally synonymous in the statute, they would have provided for such overlapping authority in the 1938 Act.

This issue was specifically addressed in Section 902(c) of the 1938 Act[21] which stated:

> Nothing contained in this Act shall be construed in any way as affecting, modifying, repealing or

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[19]The contemporaneous meaning of biologics discernible from veterinarian publications between 1912-1914 indicates that biologics were considered distinct entities; these articles fail to even mention the word drug. In 1912, Dr. Higgins wrote that "biological products as we now interpret the term are preparations and treatment of diseased conditions in man and animals caused by specific infectious agents or poisons. They include normal sera, antitoxic sera, antibacterial sera, toxins, attenuated viral and bacterial vaccines." C.H. HIGGINS, *4 AM. VET. REV.*, 283 (1912). See, R.E. Spline *AM. VET. REV.* 19 and 161 (1914). Dr. A.T. Kinsley in another article listing "Veterinary Biologic Therapeutic Agents," *7 AM. J. VET. MED.*, 281 (1912), also failed to include the term drug. In addition, veterinarians interpreted the Virus, Serum, Toxin Act of 1913 to created a statutory scheme similar to, but distinct from, that created by the Virus, Serum, Toxin Act of 1902 for human biologics. D.M. CAMPBELL (Ed.), *8 AM. J. VET. MED.*, 210 (1913).

[20]The verbatium transcript of the exchange between Senators Vandenberg and Copeland can be found in *Grand Laboratories, Inc. v. Patricia Harris* 488 F. Supp. 618, 621 (S.D. 1980); 70 Cong. Rec. 5018 (1935); *LEGISLATIVE HISTORY OF THE FOOD, DRUG AND COSMETIC ACT AND ITS AMENDMENTS* (hereinafter cited as ___ Leg. Hist. ___), 4 Leg. Hist. 62.

[21]6 Leg. Hist. 474.

> superceding the provisions of the Virus, Serum, Toxin Act of July 1, 1902 . . .

In addition, the recodification of the 1902 Act into the Public Health Service (PHS) Act of 1944 also failed to grant FDA authority over human biologics through application of the 1938 Act. Congress actually deleted a provision from H.R. 4624, ultimately the 1944 PHS Act, which specifically gave FDA such dual authority.[22]

The Animal Drug Amendments of 1968 contain, at the insistance of the Secretary of Agriculture, section 902(c) which reads:

> Nothing contained in this Act shall be construed as in any way affecting, modifying, repealing or superceding the provisions of ... the virus, serum, toxin and analogous products provisions, applicable to domestic animals, of the Act of Congress, approved March 4, 1913 (37 STAT. 832-833).

21 U.S.C. § 392(b).[23]

Assuming arguendo that the two statutes—the Virus, Serum, Toxin Act of 1913 and the Federal Food, Drug and Cosmetic Act (FDCA)—are mutually exclusive, then a gap does exist between the statutes which allows the states to regulate animal biologics. FDA perceives this gap to be a "loophole", *Grand Laboratories*, 644 F.2d at 734, which must be regulated under the general authority of its Act.

The amici believe that this gap was knowingly and intentionally constructed by Congress since it permitted, under the protection of the tenth amendment, intrastate production of autogenous and local homologous vaccines responsive to farmers' local needs. The statutory language, "shall not affect," in Section § 902(c), as Judge Heaney reasoned in his dissent in *Grand Laboratories*, 660 F.2d at 1293, is not a grant of authority to FDA to regulate animal biologics as drugs, but a restriction on FDA jurisdiction.

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[22]H.R. 4624, 78th Cong., 2nd Sess. (1944).

[23]Hearing on H.R. 7655, 23 Leg. Hist. 642-644, and 24 Leg. Hist. 432-434.

Given the explicit purposes of the FDCA and the 1913 Virus, Serum, Toxin Act and their subsequent amendments creating separate regulatory schemes, the most reasonable interpretation is that the definitions are mutually exclusive. This conclusion, regarding legislative intent, is consistent with the comment by Judge Learned Hand that

> the purpose of a statutory provision is the best test of the meaning of the words chosen.

Cawley v. U.S., 272 F.2d 443, 445 (2nd Cir. 1959).

Another key element necessary to determine whether an article or item is within the statutory definition of a drug is the vendor's intent. *National Nutritional Foods Association v. FDA*, 504 F.2d 761, 789 (2nd Cir. 1974) *cert. denied*, 420 U.S. 946 (1974). The Second Circuit recognized that intent was measured by the subjective claims of the manufacturer as well as by objective evidence.

Animal biologics, over which FDA wants to exert jurisdiction, are not sold as drugs; no labeling, promotional claims, advertising or any other relevant materials makes any claims that vaccines are drugs. In the absence of "intended use" claims, other than those permissible, courts have held that such products are not drugs. *Millet, Pit and Seed Co., Inc. v. U.S.*, 436 F. Supp. 84 (E.D. Tenn, 1977) *vacated on other grounds*, 627 F.2d 1093 (6th Cir. 1980) (apricot kernels); *U.S. v. An Article . . . Sudden Change*, 409 F.2d 734 (2nd Cir. 1969) (cosmetic); *Hanson v. U.S.*, 417 F. Supp. 30 (D. Minn. 1976) *aff'd*, 540 F.2d 947 (8th Cir. 1976) (vitamin B-17); and *Rutherford v. U.S.*, 542 F.2d 1137 (10th Cir. 1976) (laetrile).

FDA asserted to the Court of Appeals that animal biologics must, by definition, be considered drugs since they are intended for the treatment of animal diseases.[24] This logic is fallacious since it blatantly ignores the "plain meaning" derived from the contemporary interpretation of the statutory language in the 1913 Virus, Serum, and Toxin Act which states that the jurisdiction extends to

> said virus, serum, toxin or analogous products manufactured within the United States and

[24]Appellant's Eighth Circuit brief at 13, *Grand Laboratories, Inc. v. Patricia Harris*, 660 F.2d 1288 (8th Cir. 1981).

> intended for use in the treatment of domestic animals . . . .

21 U.S.C. § 151.

The assertion by FDA that animal biologics are drugs and within FDA's jurisdiction directly conflicts with the statutory grant of jurisdiction to USDA intended by Congress. Therefore, in accordance with the holding in *National Nutritional Foods Association v. Mathews*, 504 F.2d 761, 789 n.35 (2nd Cir., 1974), FDA's administrative interpretations that an animal biologic is a drug must be invalidated as arbitrary and caprious and not in accordance with the Federal Food, Drug and Cosmetic Act.

In an analogous situation, FDA asserted that alcoholic beverages are food within the meaning of 21 U.S.C. 321(f).[25] This assertion failed when the court in *Brown-Forman Distillers v.Mathews*, 435 F. Supp. 5, 13 (W.D. Ky.1976) held that a specific statute is not controlled by a general one.[26] Similarly, in *Radzanower v. Touche Ross and Co.*, 426 U.S. 148 (1976) the narrow venue provisions under the National Banking Act prevailed over the more general venue provision of the Securities Exchange Act; and in *Morton v. Mancari*, 417 U.S. 535, 550-551 (1974) employment preference for Indians in Indian Reorganization Act of 1934 was not repealed by Equal Employment Opportunities Act of 1972.

If FDA's liberal definition of drug is allowed to stand, an illogical regulatory scheme will exist which Congress never intended. Intrastate sales of animal biologics will be subject to the same regulations as required by FDA for the interstate sale of drugs. Interstate sales of animal biologics will be subject to USDA licensing regulations. Duplicative federal regulatory schemes will exist merely because the same or similar products have different points of origin and destination.

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[25] "The term 'food' means (1) articles used for food or drink for man or other animals,..."

[26] The authority of the Bureau of Alcohol, Tobacco and Firearms (BATF) under 27 U.S.C. 201 *et. seq.* was held in *Brown-Forman Distillers* to be more specific than the general authority FDA asserted under 21 U.S.C. 321(f).

When the practical results are "so manifestly unreasonable that they could not be attributed to congressional design...," *U.S. v. Rutherford,* 442 U.S. 544, 555 (1979); *TVA v. Hill,* 437 U.S. 153, 187 (1977) this Court will not uphold the result. The Court of Appeals *en banc* decision fails to fully appreciate the practical effects in terms of the economic consequences that the unreasonable FDA regulatory burden will place on intrastate manufacturers.[27]

V. THE PETITIONER HAS NEVER CONCEDED THAT ANIMAL BIOLOGICS ARE DRUGS

The Court of Appeals stated in its *en banc* decision that

> assuming the product is within the words of the FDCA's definition of 'drug' (as intrastate animal biologics concededly are).

Grand Laboratories, 660 F.2d at 1290 (1981).

The Petitioner has never conceded that animal biologics were within the meaning of "drug," nor did the District Court. *Grand Laboratories,* 488 F. Supp. at 619 (S.D. 1980). The FDA asserted in its appellant brief that:

> Hence, the district court concluded that animal biologics are products intended for the treatment of animal disease. Therefore, [FDA argues] the animal biologics at issue in this case must be considered drugs.

Reliance on this statement is misplaced since it is unclear on its face who reached the conclusion that animal biologics are drugs. The Court of Appeals may have been misled to believe that the District Court had concluded that animal biologics are drugs, when in fact the opposite is true.

The District Court merely held that animal biologics are "used for the prevention or treatment of disease in animals." *Grand Laboratories,* 488 F. Supp. at 619. This conclusion is consistent with its holding that animal biologics are not drugs. Even though vaccines and drugs may be perceived to have common uses, that fact alone, does not make the products definitionally identical. Cf. *Blank v. U.S., supra* at 305.

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[27] Supra at note 16.

VI. THE TENTH AMENDMENT TO THE U.S. CONSTITUTION PRECLUDES FDA JURISDICTION BASED ON THE COMMERCE CLAUSE

The application of 21 U.S.C. 321(g)(1) to animal biologic products made wholly intrastate is beyond the meaning of the commerce clause as intended by the Constitution.[28] Regulation of intrastate animal biologic products is reserved to the states under the tenth amendment. The commerce clause powers delegated to the federal government were presented to the ratifiers as a protection from commercial self-destruction between States, and not as a weapon to usurp their powers. MADISON, *THE FEDERALIST*, No. 42; FRANKFURTER, *THE COMMERCE CLAUSE UNDER MARSHALL, TONEY AND WAITE*, 12, (1937).

The Court originally construed the scope of the Federal Food and Drug Act to be limited to instances where interstate commerce was clearly demonstrable. *Hipolite Egg Co. v. U.S.*, 220 U.S. 45 (1910); *Savage v. Jones*, 225 U.S. 501 (1910). The relationship between intrastate and interstate commerce was defined in *McDermott v. Wisconsin*, 228 U.S. 115 (1910). which held the federal jurisdiction extended over products produced in one state and shipped into another state in an "unbroken package." State jurisdiction arose when the

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[28]FDA has argued that the New Jersey component (aluminum hydroxide) added to the otherwise wholly locally made product, converts the concededly biologic product into a drug. In the first place, this argument would permit anything to become a drug—an absurd result. Secondly, the component (aluminum hydroxide) is not a drug because testimony during the hearing on the motion to dismiss the preliminary injunction showed that the aluminum hydroxide used was a reagent grade not listed in U.S.P. Therefore, the animal biologic containing reagent grade aluminum hydroxide was not a drug within the definition of 21 U.S.C. § 321(g)(1).

In any case, FDA's argument fails to recognize that several courts have held the mere listing of a component in U.S.P. is not itself conclusive on whether a product is a drug under 21 U.S.C. § 321 (g)(1). *AMP Inc. v. Gardner*, 275 F. Supp. 410 (S.D.N.Y. 1967) *aff'd* 389 F.2d 825 (2nd Cir. 1968) *cert. denied sub. nom. AMP. Inc. v. Cohen*, 393 U.S. 825 (1968). In *U.S. v. An Article of Drug ... OVA II*. 414 F. Supp. 660, (N.J. 1975) *aff'd*, 535 F.2d 1248 (3rd Cir. 1976) the court held that "recognition of an item in the U.S. Pharmacopeia, National Formulary, etc., cannot be taken literally." This view as followed in *National Nutritional Food Ass'n. v. Mathews*, 557 F.2d 325 (2nd Cir. 1977).

shipping package was broken and individual containers were offered for sale. This "original package doctrine" was eroded in *Sonnenborn Bros. v. Cureton,* 262 U.S. 506 (1922) and gave way to the "current of commerce" theory in *Stafford v. Wallace,* 258 U.S. 495 (1921).

The preeminence of the tenth amendment over the commerce clause reached its zenith in *Schechter Poultry Co. v. U.S.,* 295 U.S. 495 (1935) which held that FDA authority may not destroy the distinction which the commerce clause itself established between intra- and interstate commerce. Other decisions at this time specifically recognized the prerogative of State Legislatures to regulate intrastate activities, particularly those affecting the economic welfare of that State. *Nebbia v. N.Y.,* 291 U.S. 502 (1934); *Borden's Farm Products v. Baldwin,* 293 U.S. 194 (1934); *Baldwin v. G.A.F. Seelig,* 294 U.S. 511 (1934).

The Court in *Grand Laboratories* has the opportunity to define the extent to which FDA may encroach via the commerce clause on the tenth amendment.

The perspective of the Court as to the scope of the Federal Food, Drug and Cosmetic Act has changed in the years subsequent to *Schechter Poultry.* The change reflects concern for protection of public health in a changing technological society and has resulted in broadening FDA jurisdictional prerogatives sanctioned by a line of cases following the liberal interpretation of *Bacto-Unidisk. Weinberger v. Bentex Pharamaceuticals,* 412 U.S. 645 (1973); *Ciba v. Weinberger,* 412 U.S. 640 (1973); *Weinberger v. Hynson, Westcott and Dunning, Inc.,* 412 U.S. 609 (1973); *U.S. v. Rutherford,* 442 U.S. 544 (1979).

The amici argue that continued judicial broadening of FDA jurisdiction in the absence of requisite statutory authority must be reassessed and guidelines given by the Court. Regulation for the sake of regulation which appears, in this instance, to cover a gap or loophole between statutes should not be authorized by denial of the Writ.

The Court has begun to recognize tenth amendment constraints on the commerce clause where actions of the

federal government further erode prerogatives of the States. On this issue, the dissent by Mr. Justice Rehnquist in *Fry v. U.S.*, 421 U.S. 542, 550 (1975) which quoted a prior dissent by Mr. Justice Douglas, is instructive,

> National Government could devour the essentials of state sovereignty though that sovereignty is attested by the tenth amendment.

Maryland v. Wirtz, 392 U.S. 183, 205 (1968).

In *Wirtz*, state employee salaries, even though purely intrastate in character, could be regulated by Congress under the commerce clause. In *National League of Cities v. Usery*, 426 U.S. 833, 853 (1976), the Court explained that the preeminence of the commerce clause over the tenth amendment in *Fry* was occasioned by extremely serious problems which endangered the well-being of all component parts of the federal system which only collective action by the national government might forestall. The Court in *National League of Cities* recognized state sovereignty in setting labor standards as it had state taxing power in *New York v. U.S.*, 326 U.S. 572, 578 (1945).

Hence, Congress may not exercise its power to regulate commerce so as to force directly upon the state decisions reserved to the state. This same distinction was analyzed with respect to the eleventh amendment in *Employees v. Missouri Public Health Department*, 411 U.S. 279, 287 (1972) in which the Court declined to extend commerce clause power.

The crucial test of whether the commerce clause is dominant or recessive to the tenth amendment requires an assessment of whether collective action by the federal government is needed. *National League of Cities v. Usery, supra*, at 853. In the instant case, no collective federal action is necessary at the intrastate level.

The federal government has recognized that states, and even cities, are sometimes better able to regulate certain aspects of private industry. In *U.S. v. South-Eastern Underwriters Association*, 322 U.S. 533 (1943), the Court has construed that Congress intended to facilitate such in relation to fire insurance. Here, the appropriate balancing test was

> whether, in each case, the competing demands of the state and national interests involved can be accommodated.

322 U.S., at 548

Accord, *South Carolina State Highway Dept. v. Barnwell Bros.*, 303 U.S. 177 (1938) (state statute regulating size and weight of trucks); *California v. Thompson*, 313 U.S. 109 (1940) (state statute requiring license for agents negotiating intra- and interstate commerce); and *Parker v. Brown*, 317 U.S. 341 (1942) (state statute setting price of agricultural commodity within state).

This Court observed that "the state may regulate matters which because of their number and diversity may never be adequately dealt with by Congress." *Southern Pacific Co. v. Arizona*, 325 U.S. 761, 767 (1944). This conclusion is instructive and quite relevant to intrastate animal biologic manufacturers and *Grand Laboratories*. The amici believe that the animal drug regulations are too inflexible to permit rapid preparation of autogenous and local homologous vaccines which are recognized by veterinarian authorities as the most effective method to control many bacterial and viral diseases of animals.

CONCLUSION

The Writ of Certiorari sought by the Petitioner, Grand Laboratories, Inc., should be granted because significant jurisdictional and constitutional questions exist that warrant a review of the judgment of the Eighth Circuit Court of Appeals.

Respectfully submitted,

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Amicus Brief

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No. 81-1428

IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1981

GRAND LABORATORIES, INC.,

Petitioners,

v.

RICHARD S. SCHWEIKER, SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondents.

BRIEF AMICI CURIAE OF ATTORNEYS GENERAL OF THE STATES OF SOUTH DAKOTA, NORTH CAROLINA, ALABAMA, OREGON, PENNSYLVANIA, ILLINOIS, NEW MEXICO, LOUISIANA, VERMONT, WEST VIRGINIA AND OHIO, AND THE SECRETARY OF AGRICULTURE OF THE STATE OF IOWA IN SUPPORT OF PETITION FOR CERTIORARI TO THE COURT OF APPEALS FOR THE EIGHTH CIRCUIT

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QUESTION PRESENTED

Whether the United States Food and Drug Administration has concurrent jurisdiction with that of the States to regulate animal biologics that are manufactured and sold wholly within a single State.

TABLE OF CONTENTS

	PAGE
QUESTION PRESENTED	i
TABLE OF CONTENTS	ii
TABLE OF AUTHORITIES	iii
INTEREST OF AMICI CURIAE	1
REASONS FOR GRANTING THE WRIT	4
CONCLUSION	18
APPENDIX	A-1

TABLE OF AUTHORITIES

CASES:	PAGE
Animal Health Institute v. USDA, 487 F.Supp. 376, 379 (D. Colo. 1980)	5
Boston Sand Co. v. United States, 278 U.S. 41, 48	9
Ferguson v. Skrupa, 372 U.S. 726, 729-732 (1963)	13
Grand Laboratories, Inc. v. Harris, 488 F.Supp. 618 (1980), 644 F.2d 729, reh. en banc at 660 F.2d 1288 (1981)	7, 8, 11
Lochner v. New York, 198 U.S. 45 (1905)	12
United States v. American Trucking Assns., 310 U.S. 534, 542-44	9
United States v. An Article of Drug. . . Bacto-Unidisk. . ., 394 U.S. 784 (1969)	10
United States v. Fisher, 2 Cranch 358, 385-86	9
United States v. Monia, 317 U.S. 424, 431-432 (1943)	8
United States v. Sullivan, 332 U.S. 689 (1948)	12
Williamson v. Lee Optical Co., 348 U.S. 483, 488 (1955)	13

STATUTES:

§ 10 of the 1906 Food and Drug Act, Ch. 31915, 34 Stat. 768 et seq. 12

§ 301(k) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 331(k), as amended in 1948 12

Drug and Cosmetic Act, 21 U.S.C. § 301 et seq. 7

South Dakota Codified Laws, Chapter 39-18, "Animal Remedies" (1977 Revision, as amended 1981) 3

Virus, Serum, Toxin Act of 1913 (VSTA) 21 U.S.C. § 151-158 15

MISCELLANEOUS:

2d Ed., 294-300: Amos, The Interpretation of Statutes, 5 Camb. L.J. 163 8

7 Legislative History of the Food, Drug and Cosmetic Act 709 12

Animal Biologics Act of 1978, H. R. 14318 (95th Cong.), 124 Cong. Rec. 37213 (1978) 6

Davies, The Interpretation of Statutes, 35 Col. L. Rev. 519) 8

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INTEREST OF AMICI CURIAE

A prosperous agricultural and livestock industry is vital to the economy of the State of

South Dakota as well as other Amicui Curiae. State authcrities recognize the importance of locally produced animal biologics which may be produced promptly to meet the immediate and every changing disease conditions of livestock.

The ability of intrastate laboratories to produce products for predominantly local problems will be seriously impaired if not eliminated by Federal regulation. Presently intrastate laboratories can respond within days to an outbreak of a potentially epedemic animal disease with vaccines developed from a strain of the specific bacteria which are therefore more effective. Federal regulation with its attendant time delays would severely hamper the ability of farmers and the States to promptly control an outbreak of an animal disease. Such regulation would also limit the range of biologic products that could be produced within the States to meet their local needs.

Amici Curiae have an interest in protecting their sovereignty with respect to an intrusion by the Federal government into the field of local veterinary medicine, a province traditionally reserved to the States. These animal biologics are developed and used entirely within the respective States. Federal regulation of products which are purely intrastate in character, without a Congressional finding of an effect on interstate commerce, would result in an impermissible intrusion into the duty and right of the States to protect their own citizens. Given the comprehensive nature of the regulation of South Dakota and the other Amici Curiae in this area,[1] Federal regulation and its accompanying delay is redundant. The harm of such additional regulation would more than outweigh any possible benefit.

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[1] See, e.g. South Dakota Codified Laws, Chapter 39-18, "Animal Remedies" (1977 Revision, as amended 1981). This chapter provides for comprehensive regulation of the production and sale of animal biologics in South Dakota. To obtain a

REASONS FOR GRANTING THE WRIT

1. The Decision Of The Eighth Circuit Court of Appeals Is Based On Philosophical Views That Are Inconsistent With Our Federalist System Of Government.

For sixty-nine years the United States Department of Agriculture (USDA) and the various State Departments of Agriculture have shared responsibility for the regulation of the manufacture and sale of animal biological products in the United States.[2] The Federal government, as was

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license, manufacturers must submit an application, proposed label, and if requested, a sample of the product, to the South Dakota Secretary of Agriculture. Registration of an animal biologic must be renewed annually. The Secretary of Agriculture may refuse to register or revoke the registration of an animal biologic if it is not efficacious. Misbranding and adulteration are broadly defined and are prohibited. The Secretary can require testing of any product and may publish the results. The Secretary has investigative power including on-site inspection and may withhold any article from sale. The chapter also provides for both criminal and civil penalties for violation of its provisions.

A brief summary of the statutes of the other Amici Curiae is set forth as an Appendix hereto.

[2] Although there are a limited number of national laboratories which mass-produce biological products for marketing in interstate commerce, it

intended by Congress,[3] has regulated only such products which are sold in interstate commerce. The States have regulated the manufacture and sale of such products on an intrastate basis. In 1979, apparently as the result of pressure placed upon the agency by the Federally regulated

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appears that a much wider variety of animal biologics are prepared by veterinarians for use in their practices, or by small laboratories operated or supervised by veterinarians specializing in microbiology, which prepare biological products primarily for other veterinarians. Inasmuch as the localized production of animal biological products is closely intertwined with the practice of veterinary medicine, this is an area of commerce that has traditionally been regulated by the United States pursuant to the police power.

[3] In 1978, the trade association of the Federally regulated manufacturers of animal biologics filed a declaratory judgment action against the United States Department of Agriculture, alleging that USDA had jurisdiction to regulate "intrastate" animal biologics. Animal Health Institute v. USDA, 487 F.Supp. 376 (D. Colo. 1980). Judge Kane upheld USDA's long-standing administrative interpretation that the Virus, Serum, Toxin Act of 1913 grants authority to regulate only those animal biologics that are shipped in interstate commerce and noted that such an interpretation "follows the intent of Congress." 487 F.Supp. at 379.

laboratories[4] rather than any perceived need to protect the public health,[5] the United States Food and Drug Administration (FDA) announced a "pilot program" to commence regulation of animal biologics produced and sold on a wholly intrastate basis. The legislative history of the Federal Food,

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4 In a Memorandum dated July 17, 1979, (Trial Exhibit B, Tr. p. 42) which was the basis for FDA's entry into the animal biologics area, the reason given for this initiative was "[w]e have had some complaints that not being subject to USDA licensing provides [intrastate] firms with unfair advantage over licensed interstate manufacturers. Furthermore, we know nothing about the products or conditions of their manufacture by these firms."

5 In a written statement issued by Representative Wampler upon introduction of the Animal Biologics Act of 1978, H. R. 14318 (95th Cong.), a measure which was not acted upon but which would have extended USDA jurisdiction over intrastate biologics manufactures, but with delegation of certain authority to the States, Representative Wampler explained that his concern was not only the need for additional regulation, but also his concern that the Food and Drug Administration appeared to be moving into this area, and that if additional regulation was required, USDA, not FDA, should be given such authority. 124 Cong. Rec. 37213 (1978).

Drug and Cosmetic Act, 21 U.S.C. § 301 et seq. (FDCA) indicates no Congressional intent to regulate animal biologics pursuant to that Act.[6] Nonetheless, in response to Grand Laboratory's Complaint alleging that FDA had no jurisdiction in this area, FDA argued to the District Court, in essence, that while the interstate production and sale of animal biologics is the sole province of USDA, the regulation of such products produced by local laboratories for sale on a wholly intra-state basis was intended by Congress to be shared between the States and FDA. The District Court, 488 F.Supp. 618, correctly noted that there was "little logical appeal" to an interpretation of the FDCA that which would place Federal jurisdiction to regulate a product when it is sold

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[6] The opinion of District Judge Nichol sets forth in detail the legislative history of the statutes in question, which clearly demonstrates that the FDCA was never intended by Congress to apply to animal biologics.

in interstate commerce in one Federal agency and jurisdiction with a different Federal agency when that same product is distributed on an intrastate basis. Nonetheless, the Eighth Circuit Court of Appeals, relying upon the supposed "plain meaning" of the FDCA,[7] reversed the District Court's judgment and held that FDA has jurisdiction to regulate "intrastate" animal biologics. 660 F.2d 1288.

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[7] This case aptly illustrates the dangers involved in relying on the supposed "plain meaning" of statutory language while ignoring the legislative history of the provision involved. As Justice Frankfurter stated (in dissent) in United States v. Monia, 317 U.S. 424, 431-432 (1943):

> This question cannot be answered by closing our eyes to everything except the naked words of the [Statute]. The notion that because the words of a statute are plain, its meaning is also plain, is merely pernicious oversimplification. It is a wooden English doctrine of rather recent vintage (see Plucknett, A Concise History of the Common Law, 2d Ed., 294-300: Amos, The Interpretation of Statutes, 5 Camb. L.J. 163; Davies, The Interpretation of Statutes, 35 Col. L. Rev. 519), to which lip

As is pointed out in Judge Heaney's dissenting opinion, such a construction of the FDCA is directly contrary to the applicable legislative history and FDA's own long-standing administrative interpretation of its jurisdiction. Perhaps even more important than the majority's obvious misreading of the particular statute in question is the curious philosophical view of the Federalist

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> service has on occasion been given here, but which since the days of Marshall this Court has rejected, especially in practice. E.g., United States v. Fisher, 2 Cranch 358, 385-86; Boston Sand Co. v. United States, 278 U.S. 41, 48; United States v. American Trucking Assns., 310 U.S. 534, 542-44. A statute, like other living organisms, derives significance and sustenance from its environment, from which it cannot be severed without being mutilated. Especiallly is this true where the statute, like the one before us, is part of a legislative process having a history and a purpose. The meaning of such a statute cannot be gained by confining inquiry within its four corners. Only the historic process of which such legislation is an incomplete fragment-that to which it gave rise as well as that which gave rise to it-can yield its true meaning. And so we must turn to the history of [the statute at issue in the case].

system of government on which the opinion is based. The majority, in drawing an analogy to this Court's decision in United States v. An Articie of Drug. . .Bacto-Unidisk. . ., 394 U.S. 784 (1969), states as follows:

> The significance of this holding for present purposes is enhanced when it is recalled that the effect of a contrary holding in Bacto-Unidisk would probably not have been to exempt the discs from regulation altogether, since, if they had not been held to be "drugs", they would almost certainly have been considered "devices", and thus subject to regulation, though to a lesser extent, under another provision of the statute. Here, by contrast, a holding that animal biologics are not "drugs" would leave those substances, in cases where they are not actually shipped in their finished form across state lines, entirely free of all federal regulation. 660 F.2d at 1291.

Without any notion of the practical considerations that weigh in favor of regulating the manufacture of the local production of veterinary biologics at the State level, the majority appears to assume, for unstated public policy reasons, that Federal regulation--regardless of which

agency has the responsibility--is preferable to State regulation. The majority then goes on to conclude as follows:

> It is perfectly true that Congress can act to cure the anomaly of FDA regulation of intrastate animal biologics, if it is an anomaly. It is equally true that Congress could overrule a holding by the courts that the Food and Drug Administration has the power to regulate animal biologics sold intrastate. The real question is, who shall bear the risk that, for reasons of inertia or otherwise, Congress may not act at all? We think it better that the risk be borne by the private parties seeking to avoid all federal regulation, rather than by the public agency seeking to defend the public health . . . 660 F.2d at 1292.

In the above-quoted passage the Court of Appeals majority reveals the underlying philosophical views upon which its decision is based: that in matters where a Federal agency alleges an interest in public health, the courts should assume, absent evidence to the contrary, that Congress intends there to be comprehensive Federal regulation, and that Federal statutes should be construed accordingly.

There was a time in American history, which extended well into the twentieth century, during which the Federal judiciary placed severe limits on economic regulation in the United States, both interpreting the commerce clause in a manner that placed restrictions on the scope of Federal regulatory programs,[8] and striking down State laws that did not conform to the judiciary's view concerning the proper scope of such regulation.[9]

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[8] The limited scope of § 10 of the 1906 Food and Drug Act, Ch. 31915, 34 Stat. 768 et seq., which applied Federal regulatory authority to "original unbroken packages" that had travelled in interstate commerce, is illustrative of this view. § 301(k) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 331(k), as amended in 1948, made it clear that once FDA has jurisdiction over a product that travels in interstate commerce it does not lose that jurisdiction once the product comes to rest in a single state. 7 Legislative History of the Food, Drug and Cosmetic Act 709. See United States v. Sullivan, 332 U.S. 689 (1948).

[9] See, e.g., Lochner v. New York, 198 U.S. 45 (1905). The concept that State laws regulating business and industrial conditions should be subject to being stricken by the judiciary because they appear to be unwise, improvident or out of harmony with a particular school of thought is, of

While we do not here argue for a return to such a philosophy, it does appear that in this case the pendulum has been permitted to swing to an extreme in the opposite direction. In doubtful cases, the Eighth Circuit Court of Appeals would now place the burden on the regulated to show that Federal regulation was not intended by Congress, rather than placing the burden on the Federal government to demonstrate the existence of regulatory jurisdiction. Such a burden of proof is inconsistent with our Federal system of government.

The United States Constitution grants to Congress plenary authority to regulate commerce among the several States. We recognize that should Congress desire to extend Federal authority to regulate the intrastate production and sale of animal biologics, upon an adequate showing of

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course, no longer recognized. See Ferguson v. Skrupa, 372 U.S. 726, 729-732 (1963); Williamson v. Lee Optical Co., 348 U.S. 483, 488 (1955).

effect upon interstate commerce, it clearly could do so. However, in the absence of clear evidence of Congressional intent to extend the commerce power to regulate an area of intrastate commerce, it is respectfully submitted that the assumption should be made that Congress has not determined that such Federal regulation is necessary, and control of that area of commerce therefore continues to be reserved to the States.

II. The Decision Below Further Threatens To Disrupt Seriously The Present Regulatory System Governing Animal Biologics.

Circuit Court Judge Heaney's dissenting opinion takes note of the lack of logic to a construction of Federal law governing animal biologics that would result in two Federal agencies developing duplicative expertise to regulate products that are only distinguishable by their point of destination. Even the dissent, however, overlooks a point that is of equal significance: that the intrastate products in question are already regulated by the States.

The decision below creates a number of complex questions concerning both the scope of FDA's authority over intrastate biologics and the continuing viability of State regulation in this area. It would appear, for example, as a matter of common sense, that the licensing provisions of the FDCA could not be applied to intrastate animal biologics. A Federal license implies a license to sell in interstate commerce. Yet by its own admission FDA has no authority over such products that enter into interstate commerce. Further, the Virus, Serum, Toxin Act of 1913 (VSTA) 21 U.S.C. § 151-158, makes it a Federal crime to transport animal biologics in interstate commerce unless under license by USDA. There is no exemption in the VSTA for FDA-licensed animal biologics. Thus even if FDA were to be found to have licensing authority in this area, the applicants for such licenses would nevertheless be required under the VSTA to either limit their sales to the State of manufacture or to

obtain a license from USDA as well. Other complex questions include, for example, whether the use by an intrastate laboratory of a single interstate ingredient in one of its products is sufficient to give FDA jurisdiction over the entire laboratory? Further, what effect will Federal jurisdiction in this area have on the regulatory programs of the various States?

Had these questions been raised before the Congress in the process of framing a Federal statute to improve the regulation of animal biologics, the appropriate Congressional committee, in the process of holding public hearings, would no doubt have had the benefit of the advice and comments of farmers, the veterinarian profession, Federal and State regulatory officials, the academic community, consumer groups and other affected parties. Not only would need for additional regulation have been analyzed, but also the adverse effect on inflation that may result from

increased regulatory costs that necessarily must be passed on to consumers could have been balanced against the potential for public health benefits of greater regulation.[10] These are issues that Congress is well equipped to deal with. By the application of a statute Congress enacted to cover drugs to animal biologics - which are a totally different type of product which involve considerations never dealt with by Congress in framing the FDCA -- the Court of Appeals has created more problems than it has solved.

For nearly seven decades USDA and the States have regulated adequately the production and sale of animal biologics. The decision of the Court below now threatens to disrupt that long-maintained Federal-State balance, without any guidance to either FDA or the States as to where

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[10] Congress could also have considered whether the effect on interstate commerce of the production of intrastate animal biologics is substantial enough to warrant Federal regulation. A judgment that the judiciary is not well equipped to make.

the boundaries between Federal and State regulation in this area are to be drawn. We respectfully submit that from the legislative history of the Federal statutes governing drugs and animal biologics, it is clear that Congress has intended that regulation of intrastate biologics continue to be reserved to the States, and that if a change in the present regulatory system is required, Congress, not the courts, should so determine.

CONCLUSION

For the foregoing reasons, the Amici Curiae submit that the opinion below contravenes the clear Congressional intent that regulation of intrastate animal biologics be vested exclusively with the States, and that the Court should issue a Writ of Certiorari to the Eighth Circuit Court of Appeals.

Respectfully submitted,

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Appendix

APPENDIX

APPENDIX

NORTH CAROLINA

The State of North Carolina recently enacted "The North Carolina Biologics Law of 1981." This is a comprehensive statute regulating the production and sale of animal biologics in the State. The statute, at 106-710 provides for licensing either by the North Carolina Department of Agriculture, or the United States Department of Agriculture.

North Carolina also has a separate and distinct statute governing food, drugs and cosmetics. Chapter 106-121, N.C. Rev. Stat. That law defines the term "drug" at 106-121(6) in a manner which is identical to that contained in the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 321(g)(1).

ALABAMA

In Alabama, the State Board of Agriculture and Industries is delegated the authority to make

rules and regulations governing the manufacture, sale, distribution, handling and keeping and use of all veterinary or biological products and serums. § 2-15-172, Ala. Rev. Stat.

In addition, Alabama has a comprehensive statute governing food, drugs, and cosmetics. 20-1-1 et. seq., Ala. Rev. Stat.

OREGON

In Oregon, animal biological products are required by the State Department of Agriculture, pursuant to 596.010, et. seq., Oregon Rev. Stat. Biologics not approved for general use by the United States Department of Agriculture pursuant to ORS 596.065.

Oregon also has a comprehensive statute regulating "drug" products, which is set forth at ORS 689.010 et. seq., and which is administered by the State Board of Pharmacy.

PENNSYLVANIA

In Pennsylvania, the sale of biological products is restricted to those approved by either

the Pennsylvania State Livestock Sanitary Board, or in the alternative, the United States Department of Agriculture. 3 PA. Code § 428. "Drugs" in Pennsylvania are regulated pursuant to "The Controlled Substance, Drug, Device and Cosmetic Act of 1972", 35 PA Code § 780-101. This statute provides a comprehensive regulatory scheme for drugs, patterned on the Federal Food, Drug and Cosmetic Act.

ILLINOIS

In Illinois, the production and sale of animal biologics is regulated pursuant to specific statutes dealing with efforts to eradicate particular diseases. For example, the Bovine Brucellosis Eradication Act, 8 Ill. Rev. Stat. 134 regulates Brucellosis Vaccines. Specifically, § 146 of that statute provides that the use of vaccines containing Brucella Microorganisms shall be limited to those approved by the Illinois Department of Agriculture or the United States Department of

Agriculture. Similarly, swine diseases are regulated pursuant to the Swine Disease Control and Eradication Act, 8 Ill. Rev. Stat. § 501 et. seq. Under that statute, at § 508, only those vaccines are permitted to be used in connection with hog cholera as the director "considers necessary when it is considered in the best interest of the livestock industry of the State."

Illinois also has a comprehensive Food, Drug and Cosmetic Act, which became effective January 1, 1968. 56 1/2 Ill. Rev. Stat. § 501 et. seq. At § 502.4 of that statute, the definition of the term "drug" tracks that of the Federal Food, Drug and Cosmetic Act. 21 U.S.C. 321(g)(1). That Statute is administered by the Director of Public Health.

NEW MEXICO

The State of New Mexico regulates both biological products and drugs pursuant to the New Mexico Drug and Cosmetic Act, 26-1-2, New

Mexico Statutes Annotated. All such products in New Mexico are regulated by the New Mexico Board of Pharmacy.

LOUISIANA

The State of Louisiana regulates both drugs and biologics pursuant to the same statute, the "State Food, Drug and Cosmetic Law," 40 La. Rev. Stat. § 601 et. seq. The statute is administered by the State Board of Health.

VERMONT

In Vermont, the distribution of animal biological products is restricted to licensed graduate veterinarians, unless approval is first granted in a permit issued by the Commissioner of Agriculture. The applicable statute is Title 6, Chapter 115, § 1731 et. seq., entitled "Veterinary Medicines." The statute is administered by the Commissioner of Agriculture, and violation of this statute is a misdemeanor, carrying a maximum prison term of six months, and a maximum fine of $200.

The State of Vermont regulates animal drugs pursuant to Chapter 82, § 4051 et. seq., entitled "Labelling of Foods, Drugs, Cosmetics and Hazardous Substances." § 4051(e) defines the term "drug" in the same manner as does the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(g)(1). In Vermont the regulation of "drugs" is vested in the State Board of Health.

WEST VIRGINIA

In West Virginia, § 19-9-12 of the West Virginia Code restricts the sale of animal biologics in the State to those approved by the United States Department of Agriculture. In addition, the sale of unattenuated hog cholera virus can be conducted in the State pursuant to West Virginia Code 19-9-12A only upon special written permit issued by the Commissioner of Agriculture.

In West Virginia, drugs are regulated pursuant to West Virginia Code 16-7-1, which prohibits the manufacture or sale of adulterated drugs.

OHIO

In Ohio, the sale of animal biological products is governed by the Livestock Remedy Act, Title 9, § 923.21 et. seq., Ohio Rev. Code. That statute is administered by the Director of Agriculture.

The State of Ohio also has a comprehensive statute regulating the production and sale of "drugs," which is found at § 3715.01 et. seq. of the Revised Code. The Ohio Food, Drug and Cosmetic Act is administered by the Ohio Board of Pharmacy.

IOWA

The State of Iowa regulates animal biological products pursuant to Chapter 166, of the Iowa Code. The Iowa statute regulating animal biologics is administered by the Department of Agriculture, and includes licensing, inspection, and sampling authority.

The State of Iowa also maintains a separate drug and cosmetic act, which is found at 203A of the Iowa Code. This statute, as is indicated by § 203A.1, "Intent of Law," is to declare that the laws of Iowa and that of the Federal Food, Drug and Cosmetic Act are uniform. The Iowa Act is patterned closely after that of the Federal Food, Drug and Cosmetic Act, and is administered by the Iowa Board of Pharmacy Examiners.